Federal Register

Thursday,
November 1, 2001

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 405 et al.

Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, and 415

[CMS–1169–FC]

RIN 0938–AK57

Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period makes several changes affecting Medicare Part B payment. The changes affect: refinement of resource-based practice expense relative value units (RVUs); services and supplies incident to a physician's professional service; anesthesia base unit variations; recognition of CPT tracking codes; and nurse practitioners, physician assistants, and clinical nurse specialists performing screening sigmoidoscopies. It also addresses comments received on the June 8, 2001 proposed notice for the 5-year review of work RVUs and finalizes these work RVUs. In addition, we acknowledge comments received on our request for information on our policy for CPT modifier 62 that is used to report the work of co-surgeons. The rule also updates the list of certain services subject to the physician self-referral prohibitions to reflect changes to CPT codes and Healthcare Common Procedure Coding System codes effective January 1, 2002. These refinements and changes will ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 modernizes the mammography screening benefit and authorizes payment under the physician fee schedule effective January 1, 2002; provides for biennial screening pelvic examinations for certain beneficiaries effective July 1, 2001; provides for annual glaucoma screenings for high-risk beneficiaries effective January 1, 2002; expands coverage for screening colonoscopies to all beneficiaries effective July 1, 2001; establishes coverage for medical nutrition therapy services for certain beneficiaries effective January 1, 2002; expands payment for telehealth services effective October 1, 2001; requires certain Indian Health Service providers to be paid for some services under the physician fee schedule effective July 1, 2001; and revises the payment for certain physician pathology services effective January 1, 2001. This final rule will conform our regulations to reflect these statutory provisions.

In addition, we are finalizing the calendar year (CY) 2001 interim RVUs and are issuing interim RVUs for new and revised procedure codes for calendar year (CY) 2002. As required by the statute, we are announcing that the physician fee schedule update for CY 2002 is −4.8 percent, the initial estimate of the Sustainable Growth Rate (SGR) for CY 2002 is 5.6 percent, and the conversion factor for CY 2002 is $36.1992.

DATES: *Effective date:* This rule is effective January 1, 2002.

Comment date: We will consider comments on the Clinical Practice Expert Panel data, the physician self-referral designated health services identified in Table 8, and the interim RVUs for selected procedure codes identified in Addendum C if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 31, 2001.

ADDRESSES: Mail written comments (1 original and 2 copies) to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1169–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

To insure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them. If you prefer, you may deliver your written comments (1 original and 2 copies) by courier to one of the following addresses: Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–8013 or Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Comments mailed to the two above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–1169–FC.

For information on viewing public comments, please see the beginning of the Supplementary Information section below.

FOR FURTHER INFORMATION CONTACT: Carolyn Mullen, (410) 786–4589 or Marc Hartstein, (410) 786–4539 (for issues related to resource-based practice expense relative value units).

Carlos Cano, (410) 786–0245 (for issues related to screening sigmoidoscopies).

Paul W. Kim, (410) 786–7410 (for issues related to incident to services).

Rick Ensor, (410) 786–5617 (for issues related to screening mammography).

Bill Larson, (410) 786–4639 (for issues related to screening pelvic examinations, screening for glaucoma, and coverage for screening colonoscopies).

Bob Ulikowski, (410) 786–5721 (for issues related to the payment for screening colonoscopies).

Mary Stojak, (410) 786–6939 (for issues related to medical nutrition therapy).

Joan Mitchell, (410) 786–4508 (for issues related to the payment for medical nutrition therapy).

Craig Dobyski, (410) 786–4584 (for issues related to telehealth).

Terri Harris, (410) 786–6830 (for issues related to Indian Health Service providers).

Jim Menas, (410) 786–4507 (for issues related to anesthesia and pathology services).

Joanne Sinsheimer (410) 786–4620 (for issues related to updates to the list of certain services subject to the physician self-referral prohibitions).

Diane Milstead, (410) 786–3355 (for all other issues).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at 7500 Security Blvd, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 5 p.m. Please call (410) 786–7197 to make an appointment to view the public comments.

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Information on the physician fee schedule can be found on our homepage. You can access these data by using the following directions:

1. Go to the CMS homepage (http://www.cms.hhs.gov).
2. Click on ''Professionals.''
3. Under the heading ''Physicians and Health Care Professionals,'' click on ''Medicare Coding and Payment Systems.''
4. Select Physician Fee Schedule.

Or, you can go directly to the Physician Fee Schedule page by typing the following: *http://www.hcfa.gov/medicare/pfsmain.htm.*

To assist readers in referencing sections contained in this preamble, we are providing the following table of contents. Some of the issues discussed in this preamble affect the payment policies but do not require changes to the regulations in the Code of Federal Regulations. Information on the regulation's impact appears throughout the preamble and is not exclusively in section XIII.

Table of Contents

In addition, because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

AMA American Medical Association
BBA Balanced Budget Act of 1997
BBRA Balanced Budget Refinement Act of 1999
CF Conversion factor
CFR Code of Federal Regulations
CPT [Physicians'] Current Procedural Terminology [4th Edition, 1997, copyrighted by the American Medical Association]
CPEP Clinical Practice Expert Panel
CRNA Certified Registered Nurse Anesthetist
E/M Evaluation and management
EB Electrical bioimpedance
FMR Fair market rental
GAF Geographic adjustment factor
GPCI Geographic practice cost index
GDP Gross Domestic Product
CMS Centers for Medicare & Medicaid Services
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
HHS [Department of] Health and Human Services
IDTFs Independent Diagnostic Testing Facilities
MCM Medicare Carrier Manual
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MGMA Medical Group Management Association
MSA Metropolitan Statistical Area
NAMCS National Ambulatory Medical Care Survey
NCD National coverage determination
PC Professional component
PEAC Practice Expense Advisory Committee
PPAC Practicing Physicians Advisory Council
PPS Prospective payment system
RUC [AMA's Specialty Society] Relative [Value] Update Committee
RVU Relative value unit
SGR Sustainable growth rate
SMS [AMA's] Socioeconomic Monitoring System
TC Technical component

I. Background

A. Legislative History

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services.'' This section provides for three major elements: (1) a fee schedule for the payment of physicians' services; (2) a sustainable growth rate for the rates of increase in Medicare expenditures for physicians' services; and (3) limits on the amounts that nonparticipating physicians can charge beneficiaries. The Act requires that payments under the fee schedule be based on national uniform relative value units (RVUs) based on the resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense, and malpractice expense.

Section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs may not cause total physician fee schedule payments to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to RVUs cause expenditures to change by more than $20 million, we must make adjustments to preserve budget neutrality.

B. Published Changes to the Fee Schedule

In the July 17, 2000 proposed rule (65 FR 44177), we listed all of the final rules published through November 1999 relating to the updates to the RVUs and revisions to payment policies under the physician fee schedule.

In the June 8, 2001 **Federal Register** (66 FR 31028), we published a proposed notice concerning the 5-year review of work RVUs.

In the August 2, 2001 proposed rule (66 FR 40373) we discussed revisions contained in the November 1, 2000 final rule with comment period and the following issues affecting Medicare payment under the physician fee schedule:

- We listed the revisions to payment policies under the physician fee schedule that were made in the November 2000 final rule with comment period (65 FR 65376).
- We discussed policy issues affecting Medicare payment for physicians' services, including—

—refinement of the resource-based practice expense relative value units;
—services and supplies incident to a physician's professional service;
—anesthesia base unit variations;
—recognition of CPT tracking codes; and
—nurse practitioners, physician assistants, and clinical nurse specialists performing screening sigmoidoscopies.

We also solicited comments on the payment policy for CPT modifier 62 used to report the work of co-surgeons.

In addition, the August 2, 2001 proposed rule addressed the following provisions of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA):

- Payment for the screening mammography benefit under the physician fee schedule effective January 1, 2002.
- Biennial screening pelvic examinations for certain beneficiaries effective July 1, 2001.
- Annual glaucoma screenings for high-risk beneficiaries effective January 1, 2002.
- Expansion of coverage for screening colonoscopies to all beneficiaries effective July 1, 2001.
- Coverage for medical nutrition therapy services for certain beneficiaries effective January 1, 2002.
- Expansion of payment for telehealth services effective October 1, 2001.
- Payment for some services of certain Indian Health Service providers under the physician fee schedule effective July 1, 2001.
- Revision to the payment for certain physician pathology services effective January 1, 2001.

This final rule affects the regulations set forth at Part 405, Federal health insurance for the aged and disabled; Part 410, Supplementary medical insurance (SMI) benefits; Part 411, Exclusions from Medicare and limitations on Medicare payment; Part 414, Payment for Part B medical and other health services; and Part 415, Services furnished by physicians in providers, supervising physicians in teaching settings, and residents in certain settings.

The information in this final rule finalizes information in the June 8, 2001 proposed notice and the August 2, 2001 proposed rule.

C. Components of the Fee Schedule Payment Amounts

Under the formula set forth in section 1848(b)(1) of the Act, the payment amount for each service paid under the physician fee schedule is the product of three factors—(1) a nationally uniform relative value for the service; (2) a geographic adjustment factor (GAF) for each physician fee schedule area; and (3) a nationally uniform conversion factor (CF) for the service. The CF converts the relative values into payment amounts.

For each physician fee schedule service, there are three relative values—(1) an RVU for physician work; (2) an RVU for practice expense; and (3) an RVU for malpractice expense. For each of these components of the fee schedule, there is a geographic practice cost index (GPCI) for each fee schedule area. The GPCIs reflect the relative costs of practice expenses, malpractice insurance, and physician work in an area compared to the national average for each component.

The general formula for calculating the Medicare fee schedule amount for a given service in a given fee schedule area can be expressed as:

Payment = [(RVU work × GPCI work) + (RVU practice expense × GPCI practice expense) + (RVU malpractice × GPCI malpractice)] × CF

The CF for calendar year (CY) 2002 appears in section XIII. The RVUs for CY 2002 are in Addendum B. The GPCIs for CY 2002 can be found in Addendum D.

Section 1848(e) of the Act requires us to develop GAFs for all physician fee schedule areas. The total GAF for a fee schedule area is equal to a weighted average of the individual GPCIs for each of the three components of the service. In accordance with the statute, however, the GAF for the physician's work reflects one-quarter of the relative cost of physician's work compared to the national average.

D. Development of the Relative Value System

1. Work Relative Value Units

Approximately 7,500 codes represent services included in the physician fee schedule. The work RVUs established for the implementation of the fee schedule in January 1992 were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes in a cooperative agreement with us. In constructing the vignettes for the original RVUs, Harvard worked with expert panels of physicians and obtained input from physicians from numerous specialties.

The RVUs for radiology services were based on the American College of Radiology (ACR) relative value scale, which we integrated into the overall physician fee schedule. The RVUs for anesthesia services were based on RVUs from a uniform relative value guide. We established a separate CF for anesthesia services, and we continue to recognize time as a factor in determining payment for these services. As a result, there is a separate payment system for anesthesia services.

II. Specific Proposals for Calendar Year 2002

In response to the publication of the August 2001 proposed rule, we received approximately 2,000 comments. We received comments from individual physicians, health care workers, and professional associations and societies. The majority of comments addressed the proposals related to medical nutrition therapy and the practice expense refinement.

The proposed rule discussed policies that affected the number of RVUs on which payment for certain services would be based. Certain changes implemented through this final rule are subject to the $20 million limitation on

annual adjustments contained in section 1848(c)(2)(B)(ii)(II) of the Act.

After reviewing the comments and determining the policies we would implement, we have estimated the costs and savings of these policies and added those costs and savings to the estimated costs associated with any other changes in RVUs for 2002. We discuss in detail the effects of these changes in the Regulatory Impact Analysis in section XIII.

For the convenience of the reader, the headings for the policy issues correspond to the headings used in the August 2001 proposed rule. More detailed background information for each issue can be found in the June 2001 proposed notice with comment period and the August 2001 proposed rule.

A. Resource-Based Practice Expense Relative Value Units

1. Resource-Based Practice Expense Legislation

Section 121 of the Social Security Act Amendments of 1994 (Public Law 103–432), enacted on October 31, 1994, required us to develop a methodology for a resource-based system for determining practice expense RVUs for each physician's service beginning in 1998. In developing the methodology, we were to consider the staff, equipment, and supplies used in providing medical and surgical services in various settings. The legislation specifically required that, in implementing the new system of practice expense RVUs, we apply the same budget-neutrality provisions that we apply to other adjustments under the physician fee schedule.

Section 4505(a) of the BBA amended section 1848(c)(2)(ii) of the Act and delayed the effective date of the resource-based practice expense RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from charge-based practice expense RVUs to resource-based RVUs. The practice expense RVUs for CY 1999 were the product of 75 percent of charge-based RVUs and 25 percent of the resource-based RVUs. For CY 2000, the RVUs were 50 percent charge-based RVUs and 50 percent resource-based RVUs. For CY 2001, the RVUs are 25 percent charge-based and 75 percent resource-based. After CY 2001, the RVUs will be totally resource-based.

Section 4505(e) of the BBA amended section 1848(c)(2) of the Act by providing that 1998 practice expense RVUs be adjusted for certain services in anticipation of implementation of resource-based practice expenses beginning in 1999. As a result, the statute required us to increase practice expense RVUs for office visits. For other services in which practice expense RVUs exceeded 110 percent of the work RVUs and were furnished less than 75 percent of the time in an office setting, the statute required us to reduce the 1998 practice expense RVUs to a number equal to 110 percent of the work RVUs. This reduction did not apply to services that had proposed resource-based practice expense RVUs that increased from their 1997 practice expense RVUs as reflected in the June 18, 1997 proposed rule (62 FR 33196). The services affected and the final RVUs for 1998 were published in the October 1997 final rule (62 FR 59103).

Further legislation affecting resource-based practice expense RVUs was included in the Balanced Budget Refinement Act of 1999 (BBRA) (Public Law 106–113). Section 212 of the BBRA amended section 1848(c)(2)(ii) of the Act by directing us to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations. These data would supplement the data we normally collect in determining the practice expense component of the physician fee schedule for payments in CY 2001 and CY 2002.

2. Current Methodology for Computing the Practice Expense Relative Value Unit System

Effective with services furnished on or after January 1, 1999, we established a new methodology for computing resource-based practice expense RVUs that used the two significant sources of actual practice expense data we have available—the Clinical Practice Expert Panel (CPEP) data and the American Medical Association's (AMA) Socioeconomic Monitoring System (SMS) data. The methodology was based on an assumption that current aggregate specialty practice costs are a reasonable way to establish initial estimates of relative resource costs for physicians' services across specialties. The methodology allocated these aggregate specialty practice costs to specific procedures and, thus, can be seen as a ''top-down'' approach. Discussion of the various elements of the methodology and their application follows.

a. Practice Expense Cost Pools

We used actual practice expense data by specialty, derived from the 1995 through 1998 SMS survey data, to create six cost pools—administrative labor, clinical labor, medical supplies, medical equipment, office supplies, and all other expenses. There were three steps in the creation of the cost pools. (Please note that the 1999 SMS data are being incorporated for CY 2002.)

- Step (1) We used the AMA's SMS survey of actual cost data to determine practice expenses per hour by cost category. The practice expenses per hour for each physician respondent's practice were calculated as the practice expenses for the practice divided by the total number of hours spent in patient care activities. The practice expenses per hour for the specialty were an average of the practice expenses per hour for the respondent physicians in that specialty. For the CY 2000 physician fee schedule, we also used data from a survey submitted by the Society of Thoracic Surgeons (STS) in calculating thoracic and cardiac surgeons' practice expenses per hour. (Please see the November 1999 final rule (64 FR 59391) for additional information concerning acceptance of these data.) For CY 2001, we used these STS data, as well as survey data submitted by the American Society of Vascular Surgery and the Society of Vascular Surgery. (Please see the November 2000 final rule (65 FR 65385) for additional information on the acceptance of these data.)
- Step (2) We determined the total number of physician hours (by specialty) spent treating Medicare patients. This was calculated from physician time data for each procedure code and from Medicare claims data.
- Step (3) We calculated the practice expense pools by specialty and by cost category by multiplying the specialty practice expenses per hour for each category by the total physician hours.

For services with work RVUs equal to zero (including the technical component (TC) of services with a TC and a professional component (PC)), we created a separate practice expense pool using the average clinical staff time from the Clinical Practice Expert Panel (CPEP) data (since these codes, by definition, do not have physician time) and the ''all physicians'' practice expense per hour.

b. Cost Allocation Methodology

For each specialty, we divided the six practice expense pools into two groups, based on whether direct or indirect costs were involved, and we used a different allocation basis for each group. The first group included clinical labor, medical supplies, and medical equipment. The second group included administrative labor, office expenses, and all other expenses.

(i) Direct Costs

For direct costs (including clinical labor, medical supplies, and medical equipment), we used the CPEP data as the allocation basis. The CPEP data for clinical labor, medical supplies, and medical equipment were used to allocate the costs for each of the respective cost pools.

For the separate practice expense pool for services with work RVUs equal to zero, we used adjusted 1998 practice expense RVUs as an interim measure to allocate the direct cost pools. (Please see the November 1998 final rule (63 FR 58891) for further information related to this adjustment.) Also, for all radiology services that are assigned work RVUs, we used the adjusted 1998 practice expense RVUs for radiology services as an interim measure to allocate the direct practice expense cost pool for radiology. For all other specialties that perform radiology services, we used the CPEP data for radiology services in the allocation of that specialty's direct practice expense cost pools.

(ii) Indirect Costs

To allocate the cost pools for indirect costs, including administrative labor, office expenses, and all other expenses, we used the total direct costs, as described above, in combination with the physician fee schedule work RVUs. We converted the work RVUs to dollars using the Medicare CF (expressed in 1995 dollars for consistency with the SMS survey years).

The SMS pool was divided by the CPEP pool for each specialty to produce a scaling factor that was applied to the CPEP direct cost inputs. This was intended to match costs counted as practice expenses in the SMS survey with items counted as practice expenses in the CPEP process. When the specialty-specific scaling factor exceeded the average scaling factor by more than 3 standard deviations, we used the average scaling factor. (Please see the November 1999 final rule (64 FR 59390) for further discussion of this issue.)

For procedures performed by more than one specialty, the final procedure code allocation was a weighted average of allocations for the specialties that perform the procedure, with the weights being the frequency with which each specialty performs the procedure on Medicare patients.

c. Other Methodological Issues

(i) Global Practice Expense Relative Value Units

For services with the PC and TC paid under the physician fee schedule, the global practice expense RVUs were set equal to the sum of the PC and TC.

(ii) Practice Expenses per Hour Adjustments and Specialty Crosswalks

Since many specialties identified in our claims data did not correspond exactly to the specialties included in the practice expense tables from the SMS survey data, it was necessary to crosswalk these specialties to the most appropriate SMS specialty category. We also made the following adjustments to the practice expense per hour data. (For the rationale for these adjustments to the practice expense per hour, see the November 1998 final rule (63 FR 58841)).

- We set the medical materials and supplies practice expenses per hour for the specialty of ''oncology'' equal to the ''all physician'' medical materials and supplies practice expenses per hour.
- We based the administrative payroll, office, and other practice expenses per hour for the specialties of ''physical therapy'' and ''occupational therapy'' on data used to develop the salary equivalency guidelines for these specialties. We set the remaining practice expense per hour categories equal to the ''all physician'' practice expenses per hour from the SMS survey data. (Note that in the November 2000 final rule (65 FR 65403), we increased the space allotment for therapy services to 750 square feet.)
- Due to uncertainty concerning the appropriate crosswalk and time data for the nonphysician specialty ''audiologist,'' we derived the resource-based practice expense RVUs for codes performed by audiologists from the practice expenses per hour of the other specialties that perform these services.
- For the specialty of ''emergency medicine,'' we used the ''all physician'' practice expense per hour to create practice expense cost pools for the categories ''clerical payroll'' and ''other expenses.''
- For the specialty of ''podiatry,'' we used the ''all physician'' practice expense per hour to create the practice expense pool.
- For the specialty of ''pathology,'' we removed the supervision and autopsy hours reimbursed through Part A of the Medicare program from the practice expense per hour calculation.
- For the specialty ''maxillofacial prosthetics,'' we used the ''all physician'' practice expense per hour to create practice expense cost pools and, as an interim measure, allocated these pools using the adjusted 1998 practice expense RVUs.
- We split the practice expenses per hour for the specialty ''radiology'' into ''radiation oncology'' and ''radiology other than radiation oncology'' and used this split practice expense per hour to create practice expense cost pools for these specialties.

(iii) Time Associated With the Work RVUs

The time data resulting from the refinement of the work RVUs have been, on average, 25 percent greater than the time data obtained by the Harvard study for the same services. We adjusted the Harvard study's time data to ensure consistency between these data sources.

For services with no assigned physician time, such as dialysis, physical therapy, psychology, and many radiology and other diagnostic services, we calculated estimated total physician time based on work RVUs, maximum clinical staff time for each service as shown in the CPEP data, or the judgment of our clinical staff.

We calculated the time for CPT codes (hereafter referred to as ''codes'') 00100 through 01996 using the base and time units from the anesthesia fee schedule and the Medicare allowed claims data.

3. Refinement

a. Background

Section 4505(d)(1)(C) of the BBA directed us to develop a refinement process to be used during each of the 4 years of the transition period. We did not propose a specific long-term refinement process in the June 1998 proposed rule (63 FR 30835). Rather, we set out the parameters for an acceptable refinement process for practice expense RVUs and solicited comments on our proposal. We received a variety of comments about broad methodology issues, practice expense per-hour data, and detailed code-level data. We made adjustments to our proposal based on the comments we received. We also indicated that we would consider other comments for possible refinement and that the RVUs for all codes would be considered interim for 1999 and for future years during the transition period.

We outlined in the November 1998 final rule (63 FR 58832) the steps we were undertaking as part of the initial refinement process. These steps included the following:

- Establishment of a mechanism to receive independent advice for dealing with broad practice expense RVU technical and methodological issues.
- Evaluation of any additional recommendations from the General Accounting Office, the Medicare Payment Advisory Commission (MedPAC), and the Practicing Physicians Advisory Council (PPAC).

• Consultation with physician and other groups about these issues.

We also discussed a proposal submitted by the AMA's Specialty Society Relative Value Update Committee (RUC) for development of a new advisory committee, the Practice Expense Advisory Committee (PEAC), to review comments and recommendations on the code-specific CPEP data during the refinement period. In addition, we solicited comments and suggestions about our practice expense methodology from organizations that have a broad range of interests and expertise in practice expense and survey issues.

b. Current Status of Refinement Activities

In the 1999 and 2000 final rules and the 2001 proposed rule, we provided further information on refinement activities underway, including the AMA's formation of the PEAC and the support contract that we awarded to the Lewin Group to focus on methodologic issues. In addition, in these rules, we announced actions taken and decisions made in response to the hundreds of comments received on our resource-based physician practice expense initiative. Because the transition will be completed in CY 2002 and the practice expense RVUs will then be totally resource-based, it is appropriate to recap the specific achievements reached and decisions implemented during this refinement effort to date.

(i) Use of the Top-Down Approach

Most of the physician organizations commenting agreed that this methodology was preferred for computing resource-based practice expense RVUs and that it was in accordance with the requirements of the BBA. KPMG Peat Marwick, under contract to us, reviewed the top-down methodology in which aggregate specialty costs are applied to specific procedures and concluded that it followed reasonable cost accounting principles. A 1999 GAO report concludes, ''HCFA's new approach represents a reasonable starting point for creating resource-based practice expense RVUs. It uses the best available data for this purpose and explicitly recognizes specialty differences in practice expense.'' Based on these comments and assessments, we made the decision to continue to use the top-down methodology to calculate the resource-based practice expense RVUs.

(ii) Use of the SMS Survey

The supplemental non-SMS survey data submitted by several specialties in response to the 1998 proposed rule, with the exception of the survey data from the thoracic surgeons, were not compatible with the format or methodology of the SMS. We awarded a contract to the Lewin Group to recommend criteria for the acceptance of specialty-specific practice expense data so that we could supplement the SMS data as appropriate. These recommended criteria are contained in the final report, ''An Evaluation of the Health Care Financing Administration's Resource-Based Practice Expense Methodology.'' This report is available on our web page under the same title. (Access to our web site is discussed in the **SUPPLEMENTARY INFORMATION** section above.)

The report also contains recommendations for revisions to the SMS or other surveys to efficiently meet the needs of our practice expense methodology. We augmented these recommendations and forwarded our suggestions for revisions to any future surveys to the AMA. For example, we developed supplementary survey questions that would allow us to distinguish both costs and direct patient care hours for all midlevel practitioners. We also suggested revisions that would capture the necessary information on separately billable supplies and services so that we could eliminate these costs from the specialty-specific practice expense per-hour calculations.

To obtain supplementary specialty-specific practice expense data that could be used in computing practice expense RVUs beginning January 1, 2001, we published an interim final rule on May 3, 2000 (65 FR 25664) that set forth the criteria applicable to supplemental survey data submitted to us by August 1, 2000.

We also provided a 60-day period for submission of public comments on our criteria for survey data submitted between August 2, 2000 and August 1, 2001 for use in computing the practice expense RVUs for the CY 2002 physician fee schedule.

In the November 1, 2000 final rule (65 FR 65385), we responded to comments received on the interim final rule and made modifications to the criteria for supplemental survey data that will be considered in computing practice expense RVUs for the CY 2002 physician fee schedule. These data can then be used to supplement the SMS survey data currently used to estimate each specialty's aggregate practice costs or to replace the crosswalks used for specialties not represented in the SMS.

In our November 1999 final rule, we accepted supplementary data submitted by the thoracic surgeons and, in our November 2000 final rule, we accepted survey data from the vascular surgeons that replaced the previously crosswalked practice expense per hour data for that specialty. In the November 2000 final rule, we also stated that if we received additional specialty-specific survey data before August 1, 2001 that met the criteria outlined in that rule, we would use these supplementary data in calculating the CY 2002 practice expense RVUs.

We accepted our contractor's recommendation to incorporate the latest SMS data into our practice expense per hour calculations. For CY 2001, we incorporated the 1998 SMS data into a 4-year average, and we are incorporating the 1999 SMS data into a 5-year average to calculate the CY 2002 practice expense RVUs.

We also accepted the contractor's recommendation to standardize the survey practice expense data to a common year. We adjusted the data to reflect a 1995 cost year.

We received comments that urged us to use the median SMS specialty-specific data instead of the mean, as well as comments supporting our use of the mean values. We made a decision to continue to use the mean in calculating the specialty-specific practice expense per hour. We believe that, in a small sample, using the median could eliminate outlying data from the calculation that represent real costs and thus should be considered.

(iii) CPEP Data

The AMA has formed a multispecialty sub-committee of their Relative Value Update Committee (RUC), the Practice Expense Advisory Committee (PEAC), to review the CPEP clinical staff, equipment, and supply data for all physicians' services. This multispecialty committee, which includes representatives from all major specialty societies, will then make recommendations on suggested refinements to these data. We indicated in our November 1998 final rule (63 FR 58833) that we would work with the PEAC and RUC to refine the practice expense direct cost inputs. This refinement process was supported in comments we received from almost every major physician specialty society.

In our November 1999 physician fee schedule final rule, we implemented most clinical staff time, supply and equipment refinements recommended by the RUC. For the November 2000 final rule, the RUC forwarded to us significant additional refinement recommendations that reflected multispecialty agreement on the typical resources for many important services, including visit codes, which account for

approximately 24 percent of Medicare spending for physicians' services. Again we accepted almost all of these RUC recommendations. In addition, at its October 2000, February 2001, and April 2001 meetings, the PEAC focused on refining high-volume services and on standardizing inputs across wide ranges of services. The RUC and PEAC forwarded to us recommendation on refinements for over 1,100 services. We anticipate that the pace of refinement of the CPEP inputs will continue to accelerate.

In addition to implementing most of the RUC-recommended refinements, we responded to comments on errors and anomalies in the CPEP data in both the November 1999 and November 2000 final rules. For example, we removed separately billable casting supplies and drugs from all services; we adjusted the prices of certain supplies that were clearly in error; we removed duplicated equipment from the direct inputs of the nuclear medicine codes; we added clearly essential equipment that was missing from the lithotripsy and photochemotherapy codes; we corrected anomalies in inputs within several families of codes; and we changed the crosswalks for the CPEP inputs of several codes not valued by the CPEP panels when a commenter suggested more appropriate crosswalks.

We simplified the refinement of equipment inputs by combining both the procedure-specific and overhead equipment into a single equipment category. We also deleted stand-by equipment and equipment used for multiple services at one time from the direct cost inputs because of the difficulty of allocating these costs at the code-specific level.

We are resolving issues related to averaging input costs for codes that were valued by more than one CPEP panel. While we have received comments agreeing and disagreeing with our use of mean costs, the issue is moot because we are substituting refined data for the data previously produced by multiple CPEPs.

(iv) Physician Time Data

In the November 1999 rule (64 FR 59404), we stated that, in general, requests for revisions for the procedure-specific physician times should be deferred to either the RUC process or the 5-year review process. However, we did adopt the newer data to correct the physician time for the pediatric surgery codes and made the requested revisions to correct anomalies in the times of certain psychotherapy codes.

In response to comments on the times associated with physical and occupational therapy services, we added preservice and postservice times to all of these codes.

(v) Crosswalk Issues

In response to concerns expressed by specialty societies representing emergency medicine that the SMS data did not capture the costs of uncompensated care, we crosswalked emergency medicine's cost pools for administrative labor and other expenses to the practice expense per hour for ''all physicians.''

We resolved issues related to the specialty crosswalk for nursing specialties by eliminating the separate practice expense pools for midlevel practitioners.

(vi) Calculation of Practice Expense Pools—Other Issues

We addressed concerns that potential errors in our specialty utilization data will have an effect on the calculation of practice expense RVUs. In the July 2000 proposed rule (65 FR 44178), we discussed our simulations that demonstrated that the small percentage of potential errors in our very large database have no adverse effect on specialty-specific practice expense RVUs.

We have created the zero-work pool for services with no physician work to ensure that these services are not inappropriately disadvantaged by our methodology. We have also agreed with the request of all the specialty societies that commented that their services should be moved out of the zero-work pool and into the specialty-specific pool. The specialties whose services remain in the zero-work pool have indicated that they wish their services to remain there. We plan to eliminate this separate pool for services with no physician work only when we have determined what revisions to our methodology are required so that we can value these services appropriately outside of the zero-work pool.

(vii) Calculation of Indirect Cost

We requested that our contractor evaluate various options for calculating indirect costs. The final report, referenced above, contains an analysis of the impacts of six alternative allocation methodologies. In confirming the suitability of our allocation methodology, the report concludes that ''HCFA's approach is broadly consistent with most of the alternative methods. This consistency suggests that, from a broad perspective, no other allocation methodology offers a compelling reason to abandon the current HCFA approach.''

(viii) Site-of-Service

The practice expense RVUs would be expected to be higher in the nonfacility setting, where the practitioner bears the costs of the necessary staff, supplies, and equipment, than in the facility setting. To prevent potential anomalies in our calculations due to the different mix of specialties performing a given service in different settings, we capped the practice expense RVUs for a physician service in facilities at the nonfacility practice expense level for each specific service.

In the November 1999 final rule (64 FR 59407), in response to a comment from the Renal Physicians Association, we agreed that the monthly capitated service codes should always be reported using the nonfacility designation. The site-of-service designations are not meaningful for a monthly service that may be provided in different settings for the same patient during a given month.

Although we are continuing our refinement of all practice expense RVUs, we believe that the above description of our actions to date illustrates that much has been accomplished. We also believe that it demonstrates that we have been responsive to comments from the medical community and have established a process that enables this community to participate fully in the refinement of both the specialty-specific practice expense per hour and the CPEP code-specific inputs.

4. Practice Expense Provisions for Calendar Year 2002

a. SMS Data

(i) Use of 1999 SMS Survey Data

We are currently using data from the 1995 through the 1998 SMS surveys (1994 through 1997 practice expense data) in order to calculate the specialty-specific practice expense per hour. The 1999 SMS survey data are now available. Because we want to incorporate the most recent survey data into our methodology during the transition period, we proposed in our August 2001 rule (66 FR 40377) to add this 1999 data to the 4 years of data we are currently using.

We proposed to use these 5 years of data in addition to any supplemental specialty-specific data that meet our criteria as the basis of the practice expense per hour calculations until the first 5-year review of practice expense RVUs in 2007. At that time, we anticipate that newer practice expense survey data might be available.

Comment: Specialty societies representing internal medicine, family

practice and a number of their subspecialties were opposed to using the 1999 SMS data in the calculation of the practice expense RVUs. While many of these commenters were generally supportive of incorporating the most current SMS data, they are concerned that the sample size and results from the 1999 SMS data may not warrant their inclusion. Several of these commenters indicated that the American Medical Association is on record stating that ''it normally would not provide or publish data with so few responses for some specialties.''

A number of these commenters suggested that the practice expense information from the 1999 SMS would be less reliable because the data were collected after CMS announced the new resource-based practice expense methodology in the **Federal Register**. These commenters suggested that the opportunity for ''gaming'' now exists because the public was aware that the SMS data were used to calculate Medicare payments.

One commenter noted that the practice expense per hour for cardiology dropped by 15 percent in one year and doubted that the actual change in practice expense of this magnitude could have occurred. Another commenter indicated that the cardiac subspecialty of electrophysiology is very likely not represented at all in this flawed data set.

One association that represents eye surgeons commented that the 1999 SMS survey included about half as many usable responses as the 1995 through 1997 surveys. This commenter questioned our decision to disregard responses received by mail and indicated that an already poor response rate to the survey has become even lower. Another commenter that represents ophthalmology indicated that use of 1999 data with such low response rates violates good statistical practice. The 1999 responses included only 23 ophthalmologists, while over 200 offered responses to the survey in years before 1999. Another commenter that represents gastroenterology indicated that the SMS is perhaps the best available source of data on multispecialty practice costs. However, this comment indicated that it is by no means a perfect data source for the manner in which it has been used by CMS and is even less reliable for certain specialties, such as gastroenterology. This commenter appreciates our willingness to accept supplementary data from specialties, but believes that it is our responsibility to overcome data deficiencies. We were encouraged to develop a uniform and fair process to overcome data deficiencies, without relying on individual medical specialties to provide such data.

In light of AMA's suspension of the SMS survey, this commenter urged us to discuss in the final rule our plans for updating practice expense RVUs in future years beginning with 2003, and, if need be, for replacing the SMS survey with an alternative data source. Another commenter expressed concern that the newer data from the SMS surveys will not be incorporated until the first 5-year review of practice expense RVUs in 2007; by that time, some of the practice expense data will have been in existence for 13 years.

Similarly, another commenter expressed concern that using the SMS data set from 1995 through 1999 until 2007 will mean that the data will not accurately reflect the changes in technology that will increase costs, particularly for specialties with rapid changes in technology.

Response: In response to the comment that the SMS data are not a perfect data source for developing practice expense RVUs, as we have said previously, we believe the SMS survey is the best available source of data on multispecialty practice costs. This comment was echoed by one of the same commenters that objected to including the 1999 SMS data in the practice expense methodology for determining 2002 RVUs. While we have previously acknowledged that the data have potential limitations for determining practice expense RVUs, there are no alternative data sources that are better for this purpose.

Since there are no other data on aggregate multispecialty practice costs that are better than the SMS, our only alternative would be to eliminate the SMS data from the methodology and rely solely on estimates of practice expense inputs for individual codes. We believe a better approach would be to continue using the SMS data in the practice expense methodology and to work with the physician community to develop even better data for establishing practice expense RVUs in the future.

One commenter noted that we only included telephone survey responses and not mail responses from the 1999 SMS and suggested that this decision further reduces an already low response rate. Our understanding is that the AMA, as a result of concerns about a declining number of responses to the SMS survey, used several approaches to obtain more surveys in the 1999 SMS. As part of this effort, some survey respondents received a mail survey instead of the normal telephone survey. Our review of information from the AMA suggested that there were significant differences between the mail and telephone surveys on questions related to practice expense. Since our objective has been to use a consistent approach to obtaining practice expense data for use in our methodology, we felt that it would be better to incorporate only the traditional telephone survey responses in the methodology consistent with how the data were obtained in earlier years.

While a few commenters indicated that the SMS data are not representative of a particular specialty's costs, they provided no information to support the contention. One commenter suggested that electrophysiology, a subspecialty of cardiology, was unlikely to be included in the SMS survey. Since the SMS survey draws a random sample from the AMA's Physician Masterfile, we believe all physicians are equally likely to be selected for participation in the survey. We would further note that the SMS weights response information based on known characteristics of the population to make the final figures as representative of the self-employed population as possible. As we have stated previously, we believe the SMS survey is the best source of data for specialty practice expenses. If a specialty believes that the SMS is unrepresentative of their actual practice expenses, we have established a process by which additional data can be submitted to us. To date, we have used two specialty practice expense surveys in addition to or in place of the SMS survey. We encourage specialties to use this process to provide us with additional practice expense data that improve the representativeness of the data that we are using to determine the practice expense RVUs.

One commenter doubted that cardiology practice expense could have declined as much as suggested by the 1999 SMS data. We would note that the practice expense per hour in any given year can show more variability than the change in practice expense per hour over time. While the specialty of cardiology shows some level of variability in practice expense per hour, with some years showing a higher value than the average and other years a lower value, the change in practice expense per hour including the 1999 SMS data is far more modest than that suggested by the commenter. There is a -2.0 percent change in practice expense per hour as a result of including the 1999 SMS data. As indicated below, use of the 1999 SMS data changed average specialty level payments to cardiologists by less than 0.5 percent.

We acknowledge that response rates and the number of usable responses from the 1999 SMS are lower than in prior years. Nevertheless, as we have stated previously, it is unclear to us why this alone indicates that we should reject incorporating the data. To the extent that there are few responses to the latest SMS survey, there will be less impact on a given specialty because the practice expense per hour calculation is weighted by the number of respondents from each respective year. Further, we believe inclusion of more survey data will improve the data's representativeness and lead to more stability in the practice expense per hour. The use of the 1999 SMS data appears to have little effect on the practice expense RVUs. In our August 2, 2001 proposed rule (66 FR 40397), we simulated the impact of including the 1999 SMS data on average specialty level payments. The increase or decrease in average specialty level payment was less than 0.5 percent for 29 of the 35 specialties listed, including nearly all of the specialties that expressed concern about including the latest SMS data. For 4 of the remaining 6 specialties, the increase or decrease in payments was between 0.5 and 1.0 percent. Payments for the remaining two specialties (pathology and suppliers) increased by more than 2 percent.

We are doubtful that respondents ''gamed'' responses in the 1999 SMS because of an awareness that reporting higher practice expenses would lead to increased payments from Medicare. We observed no noticeable increase in practice expense per hour from the 1999 SMS survey than from earlier years. In fact, the inflation-adjusted all-physician practice expense per hour from the 1999 SMS data is lower than the same figure from the 1998 SMS data. Further, if the concern is that physicians were aware of how the data would be used and would ''game'' responses to obtain higher payments from Medicare, our expectation would be that the number of responses in the 1999 SMS would be higher, not lower, than in prior years. For these reasons, we are doubtful that there is any reason to assume that the 1999 SMS survey would show more bias than surveys from previous years.

We welcome the comments that suggest that we develop a long-term strategy for using aggregate specialty practice expense data to make refinements to RVUs. As noted by some commenters, the AMA is no longer conducting the SMS survey in its current form. We would like to engage physician specialty societies, as well as other practitioner groups and representatives of organizations affected by Medicare physician fee schedule payments, in discussions of how to best obtain practice expense data that will be useful in updating our methodology for determining practice expense RVUs. Although it has been beneficial to use 5 years of SMS data to develop practice expense RVUs, we believe that it may not be necessary to make annual updates to aggregate specialty practice cost data if relative practice expenses do not change significantly from year to year. However, it may be beneficial to periodically review aggregate practice expenses and make changes when necessary. For instance, one commenter suggested that technological innovation may change relative expenses among services. For this reason, we believe a review of aggregate practice costs at least every 5 years is necessary. In fact, the statute requires that we review RVUs at least every 5 years. At this time, we have incorporated all of the data from the SMS surveys into the practice expense methodology. We will consider public input on the best way to obtain practice expense data for use in future practice expense calculations.

(ii) Supplemental Practice Expense Survey Data

To ensure the maximum opportunity for specialties to submit supplementary practice expense data, we proposed to accept survey data that meet the criteria set forth in the November 2000 final rule for an additional 2 years. The deadlines for submission of such supplemental data to be considered in CY 2003 and CY 2004 are August 1, 2002 and August 1, 2003, respectively.

Comment: Several commenters expressed their strong support for our decision to accept specialty-specific practice expense surveys for an additional 2 years. Specialty societies representing podiatry, pediatrics, internal medicine, rheumatology and surgery, as well as the American Medical Association (AMA) stated their agreement with this decision.

An organization representing medical colleges commented that this will send an important message to the physician community about our willingness to consider all legitimate data sources in analyses of this critical portion of payments, and one that has been a subject of controversy within the community. A specialty society representing dermatology stated that the additional time will allow specialties to collect specialty-specific data that should be useful as we determine practice expense RVUs.

The AMA and a commenter representing podiatry expressed some concern about the criteria for the acceptance of survey data and the AMA also expressed hope that we would be flexible concerning any data submitted. The commenter representing emergency medicine argued that collecting specialty-specific data would be fruitless, due to a number of stringent criteria for submitting supplemental practice expense survey data.

On the other hand, three commenters indicated that we should accept only survey data that meet our criteria. The commenter representing rheumatology stated that it is critically important that any data accepted must meet the criteria in the November 2000 final rule.

Response: We received only comments supporting this proposal, and we will be extending the period of acceptance of supplemental survey data for another 2 years, as proposed. We hope to demonstrate flexibility in helping those specialties that conduct a survey to do so successfully, and we understand that for some specialties some revision to the survey format may be necessary. For example, questions regarding uncompensated care for emergency physicians or separately billable drugs for oncologists might need to be added to a survey to determine the appropriate practice expense for these specialties. However, like several of the commenters, we believe that fairness to all can only be achieved if we consistently apply the rules for determining validity to any survey that is submitted.

Comment: A specialty society representing geriatrics expressed concern regarding the use of SMS data in formulating practice expense costs because the sample size for geriatricians is not large enough to yield reliable data. The commenter stated that smaller specialty societies will be unable to provide supplementary survey data because of expense limitations and recommended that we continue to review alternative data sources that recognize the greater resources spent in caring for frail elderly persons. The society further recommended that we consider the use of ''non-compliant'' survey data for smaller specialty groups that do not meet our stringent and costly criteria.

Response: We could not justify accepting ''non-compliant'' surveys from some specialties, due solely to the specialty's size, while holding others to a more rigorous standard. However, though we would welcome survey data from any specialty that submits a survey that meets our criteria, we do recognize that performing a survey can be costly. We, therefore, suggest that the specialty society consider in advance the extent to which any possible survey result

might actually alter the practice expense RVUs for their services. Note that we have only one payment amount for each service on the fee schedule. We have no authority to pay more to one specialty than to another for performing the same service. If a small specialty provides only a small percentage of a given service, a change in the practice expense per hour for that small specialty could have very little effect on the payment for the service. For example, if geriatricians perform mainly evaluation and management (E/M) services, even a survey that shows increased practice costs for geriatricians would not necessarily have any effect on the practice expense RVUs for E/M services because geriatricians' services would represent only a small part of the universe of E/M services. However, it is incumbent upon each specialty society to weigh both the costs and benefits to their specialty to determine whether conducting a practice expense survey would be worthwhile.

(iii) Submission of Supplemental Surveys

Three organizations submitted supplemental survey data for consideration for CY 2002. Survey data were submitted by the American Physical Therapy Association (APTA), the American Optometric Association (AOA), and the American Academy of Pediatrics (AAP). Our contractor, The Lewin Group, has evaluated the data submitted by each organization. They have recommended that we use the data submitted by APTA and AOA and reject the data submitted by AAP. The full recommendation and discussion will be made available on the CMS web site. (See the **SUPPLEMENTARY INFORMATION** section of this rule for directions on accessing our web site.)

We have decided not to use the data submitted by APTA, AOA, or AAP because none of the surveys met all of our stated criteria. In our May 3, 2000 interim final rule (65 FR 25666), we indicated that, based on our review of existing physician practice expense surveys, we believe that an achievable level of precision is a coefficient of variation (that is, the ratio of the standard error of the mean to the mean expressed as a percent) not greater than 10 percent for overall practice expenses or practice expenses per hour. For existing surveys, the standard deviation is frequently the same magnitude as the mean. We indicated in the May 2000 interim final rule that we would consider practice expenses for which the precision of practice expenses is equal to or better than this level of precision and that meet the other survey criteria. None of the surveys submitted for 2002 met the level of precision criteria; therefore, we have decided not to use the survey data.

b. CPEP Data

(i) 2000 RUC Recommendations on CPEP Inputs

In the November 2000 final rule (65 FR 65393), we responded to the RUC recommendations for the refinement of the direct inputs for 49 CPT codes and for the supply and equipment inputs for four additional services. These recommendations reflected multispecialty agreement on the typical resources for many important services, including visit codes, which account for approximately 24 percent of Medicare spending for physicians' services. We accepted almost all of these recommendations. We received the following comments on our responses to the RUC recommendations and on the PEAC/RUC refinement process:

Comment: Several specialty societies representing osteopaths, rheumatologists, neurologists, ophthalmologists, obstetricians, and gynecologists commended us for implementing the refinements submitted by the PEAC and RUC as part of the on-going refinement process. One specialty society stated that it was encouraged by the direction pursued with the physician fee schedule for 2001, because it demonstrated the ability to achieve refinement within the parameters of the fee schedule comment process. Another commenter expressed appreciation for our support of the PEAC and RUC refinement process because this relationship is critical to establishing fair and balanced payment policies.

In addition, other commenters praised our staff for being helpful in responding to the PEAC members' questions during meetings, as well as for the willingness to work with physician specialty societies toward establishing fair and appropriate reimbursement values. The RUC commented that it agreed that the PEAC has made significant progress in its ability to review and refine direct practice expense inputs for individual CPT codes.

Response: We appreciate the above comments and are also encouraged by the progress that the PEAC and RUC have made in refining the practice expense inputs.

Comment: The RUC agreed that the PEAC should continue to meet and refine the direct practice expense data. Therefore, it hopes that we will state that the practice expense RVUs will continue to be interim and subject to refinement as the PEAC continues its review. A specialty society representing ophthalmology echoed this request stating that, because the PEAC is continuing the refinement process, the interim status of the practice expense RVUs should be reaffirmed in the rule. The commenter requested that the RVUs remain interim and subject to change until 2007, that is, until the first update of the five-year review of practice expense RVUs.

Response: We are pleased that the RUC and PEAC are willing to continue the task of helping us to refine the practice expense inputs for the approximately 7,000 services in the physician fee schedule. We intend to keep the practice expense RVUs as interim as long as this refinement process is necessary. Also, as noted above, we will accept, for another 2 years, supplemental survey data that meet our criteria. During this period, we will also continue to make improvements to our practice expense methodology.

Comment: A commenter representing three ophthalmology sub-specialties, though appreciative of our implementation of the PEAC recommendations, expressed disappointment that we have not made the non-controversial revisions to correct additional errors in the CPEP database. The commenter encouraged us to explore alternative ways to improve the quality of the CPEP data without waiting for the PEAC to consider each of the thousands of alleged errors.

Response: We have made changes to the CPEP data in those instances when there was a clear anomaly in the data and when the more appropriate revision would be obvious, without the benefit of a multispecialty recommendation. However, we have found that the input and recommendations of a multispecialty group, such as the PEAC, have played a crucial role for the vast majority of suggested revisions when clinical judgment is involved.

Comment: An organization representing diagnostic imaging centers stated that it would be inappropriate for the PEAC to constitute the review body for direct cost data for technical component services, because the PEAC does not include any representatives of diagnostic imaging centers. The commenter requested that, if any of the CPEP direct cost data form the basis for future payment for technical component services, the accuracy of these data should be reviewed by representatives of centers that actually provide the services involved.

Response: We do not agree that it is inappropriate for the PEAC to review

the direct cost inputs for imaging services. The presentations for each service discussed at the PEAC are based either on surveys or panels of individuals who are familiar with the procedure in question. In addition, any of the recommendations of the PEAC that we accept are subject to review and comment by any interested party.

Comment: Societies representing surgeons, urologists, ophthalmologists, pediatrics, internists, and family physicians strongly support our acceptance of the revisions of CPEP inputs for office-based E/M services. One specialty society commented that the refined inputs for these services reflect the work of a multidisciplinary workgroup and demonstrate a major positive step toward streamlining practice expense inputs. One surgical specialty society did not fully agree that it is appropriate to use these E/M inputs to refine postsurgical visits because the direct costs associated with these visits are not necessarily comparable to the typical E/M visit. On the other hand, a primary care specialty society commented that the ''rolling'' implementation of CPEP refinement creates an anomaly because the surgical global services have not yet had these lower PEAC estimates for the E/M visits applied.

Response: We also saw the refinement of the practice expense inputs for the E/M codes as a significant milestone in the whole refinement process. These codes not only represent a sizeable portion of Medicare payments, but they also are used by most medical specialties, and, thus, most members of the PEAC had a stake in the outcome of this issue. We believe that, as a result of the extensive multispecialty discussion held by the PEAC on this issue, the recommendations on the E/M codes represent the best available estimates of the direct inputs needed for performing these services. With respect to the issue of applying these E/M inputs to the surgical global services, we will not be taking separate action now, but will be responding to the specific PEAC recommendations. We understand that it is expected that all the 90-day global surgical services will be refined by the PEAC by next year.

Comment: A specialty society representing internal medicine commented that the registered nurse (RN) and licensed practical nurse (LPN) staff mix should be used for the E/M codes rather than the RN, LPN, and medical assistant staff mix, which is less typical. The commenter also stated that we should increase the postservice clinical staff work for these services by 20 percent.

Response: We do not agree with changing the staff mix at this time, particularly because the PEAC recommendations have used this staff mix across the majority of refined services. We also have seen no evidence to suggest that the post-times for these services were undervalued.

(ii) 2001 RUC Recommendations on CPEP Inputs

We have received recommendations from the PEAC on the refinement to the CPEP inputs for over 1,100 codes. These include refinements of large numbers of orthopedic, dermatology, pathology, physical medicine, and ophthalmology services. In addition, the PEAC confirmed that there were no inputs for over 150 ZZZ-global procedures that are performed only in the facility and no supply or equipment inputs for almost 700 facility-only services with an XXX or 0-day global period. We believe this large increase in the number of CPT codes that have been refined demonstrates that the PEAC refinement process is working due to the valiant efforts of the AMA staff and the specialty societies participating in this mammoth undertaking. There is also reason to believe that the pace of refinement will continue to increase because of the steps that the PEAC is taking to create standardized packages of clinical staff time, supplies, or equipment that can be applied over a wide range of services.

We have reviewed the submitted PEAC recommendations and have accepted most of them with only minor revisions. The complete PEAC recommendations and the revised CPEP database can be found on our web site. (See the Supplementary Information section of this rule for directions on accessing our web site.)The following is a list of the only revisions we made to the PEAC recommendations:

- We substituted the multispecialty minimum visit supply package or the ophthalmology supply package for the list of individual supplies, when appropriate.
- We deleted separately billable supplies, for example, drugs, fluids, and casting supplies, when listed in the recommended supply list.
- We rounded fractions of minutes of clinical staff time to the nearest minute.
- For CPT code 52281, *cystoscopy and treatment,* we deleted the bougie a boule from the equipment list. The specialty society supplied us with the price of $105 for this item, which does not meet the minimum cost of $500 for an item to be included in the equipment list.
- For several ophthalmology services that did not involve dilation of the pupil, we consulted with the specialty society and deleted the ophthalmology visit supply package that was listed for the post-procedure visit. This package is intended for those services where dilation is necessary. The society confirmed that no supplies are needed for the post-procedure visit for these services.
- The recommendation did not specify the number of EEG electrodes for CPT code 92585, *auditory evoked potential, comprehensive.* We added seven electrodes, which is the same number assigned to the visual evoked potential code.
- The PEAC/RUC recommendations included time for the clinical staff type, ''Physical Therapy Assistant (PTA),'' which currently is not included in our CPEP input database. We are pricing the PTAs by using the Bureau of Labor Statistics wage estimates for physical therapy assistants. The base annual salary we are using will be $33,690. After factoring in benefits and adjusting this to 2001 dollars, the per minute rate will be $0.386.
- We have two concerns about the PEAC recommendations for therapy services. First, we believe that some of the duties ascribed to the physical therapy assistant are actually therapist services that are already captured in the work RVUs. Therefore, we are deleting from all the therapy codes the clinical staff time for obtaining vital signs and measurements, patient education, and phone calls. Because we believe that the resulting clinical staff times may be too low for the physical therapy and occupational therapy evaluation and reevaluation services, we are adding 7 additional minutes for the therapy aide in each of these codes. In addition, some of the occupational therapy codes contain several pieces of very expensive equipment called environmental modules. Because it is unclear how many of these modules would typically be used for each service, we are only including one module for each code that might use this equipment. We note that for three services, CPT codes 97530, 97535, and 97537, the PEAC did not submit a recommendation for equipment, presumably because of the difficulty of determining what would be typically used. In those cases, as in those with a PEAC recommendation, we are allowing for one module and some smaller equipment that was suggested by the specialty. We would hope to work with the specialty societies to obtain more precise information on the appropriate equipment for all of these therapy services.

• We note that one of the services for which we received recommendations, the casting/strapping procedure CPT code 29799, is carrier-priced. In addition, we received recommendations for two fine needle aspiration services, CPT codes 88170 and 88171, which are now deleted.

(iii) Other Comments on Refinement of CPEP Inputs

Comment: Several commenters were pleased that we finalized certain proposals regarding CPEP inputs, such as the following:

• The reinstatement of the pre-procedure clinical staff time in the facility setting for certain 0-day global services as well as pre-service time for the vitrectomy codes.

• Our decision to uphold the proposed refinements regarding inpatient dialysis CPT codes 90935 and 90945.

• The clarification of Medicare payment policy for cast supplies when used for non-fracture/dislocation procedures.

• The decision to retain Unna boot in the supplies for CPT code 29580.

• The correction of the supply list for CPT code 88104 and the establishment of a separate nonfacility practice expense RVU for CPT code 85607 in the 2001 fee schedule.

• The extension of the code-specific refinement beyond 2002.

Response: We appreciate the above comments and will strive to continue refining the practice expense RVUs in a manner that is fair and beneficial to the medical community.

Comment: An allergy clinic commented that because of our definition of a dose for CPT code 95165, *Allergy Immunotherapy,* doctors will be forced to use a dosage that could be harmful to certain patients.

Response: The definition of a dose will be used only for pricing the practice expense inputs for this service. Physicians should use their clinical judgment in determining what dose to use for any particular patient.

Comment: A commenter noted that the two codes for anal balloon sphincterplasty (CPT codes 49505 and 49510) did not have the balloon listed in the supply inputs.

Response: We agree that this was an omission and have added the balloon to the supply list for both services.

Comment: A commenter stated that there are no practice expense inputs assigned to CPT code 36533, *insertion of implantable venous access port, with or without subcutaneous reservoir,* in the nonfacility setting, because the CPEP panels priced it only in the facility. In particular, the supply inputs do not contain the cost of the catheter that is an integral part of the procedure.

Response: It is true that the original CPEP panel did not price this in the nonfacility setting; however, we subsequently crosswalked the inputs from the facility to the nonfacility setting for supplies, equipment, and clinical staff, adding clinical staff time for the intraservice period in the office. However, we agree that the catheter is an appropriate supply and have added it to the supply list for this code.

Comment: A specialty society representing podiatrists questioned why the practice expense RVUs for the nail trimming codes G0127 and CPT code 11719 are not the same. The commenter stated that they should have the same CPEP inputs since both were refined by the PEAC this year with identical inputs.

Response: The CPEP inputs are now identical for both codes, except that the supplies recommendation for CPT code 11719 does not include a surgical mask. However, none of this year's PEAC recommendations were reflected in the August 2001 proposed rule. In addition, even codes with identical CPEP inputs can have different practice expense RVUs if a different mix of specialties performs each service.

Comment: Two specialty societies representing cardiologists and electrophysiologists commented that we have allowed 60 minutes of clinical staff time to arrange for surgical procedures with a 90-day global period, but we have not yet allowed the same for 0-day global period procedures in facilities. The commenters stated that they may present specific codes to the PEAC with the recommendation that this time be recognized for these services, and they hope that we will be receptive to these recommendations.

Response: We will be glad to review any PEAC recommendations on clinical staff pre-service time for 0-day global period services in the facility setting if and when we receive them.

(iv) Repricing of Clinical Staff Wage Rates

In the August 2, 2001 proposed rule (66 FR 40378), we proposed modifications of wage rates for the clinical staff types contained in the CPEP database. Our contractor, Abt Associates, assigned the costs of the original CPEP inputs for staff, supplies, and equipment based primarily on 1994 and 1995 pricing data.

The original Abt Associates' estimates of clinical staff wage rates relied primarily on the Bureau of Labor Statistics (BLS) data. Abt's report on the CPEP cost estimation stated that, ''* * * the BLS data were considered to be the preferred data set. The BLS'' reputation for publishing valid estimates that are nationally representative led to the choice of the BLS data as the main source. If more than one data set provided an exact mapping for a receptionist, then the BLS wage was chosen over any other mapping.''

We agreed with this assessment and have used the most current BLS survey (1999) as the main source of wage data.

It should be noted that the BLS discontinued the Occupational Compensation Survey used by Abt in 1995 and now conducts the National Compensation Survey that has a breakdown of staff types different from the earlier survey. Also, this survey does not cover all the staff types contained in the CPEP data. Therefore, it was necessary for us to crosswalk or extrapolate the wages for several staff types using supplementary data sources for verification whenever possible.

We used three other data sources to price wages of staff types that were not referenced in the BLS data:

• The American Society of Clinical Pathologists' survey of laboratory staff salaries (found at *www.ascp.org*).

• The survey performed by the American Academy of Health Physics and the American Board of Health Physics (found at *www.hps1.org*).

• The national salary data from the *Salary Expert,* an Internet site that develops national and local salary ranges and averages for thousands of job titles using mainly government sources. (A detailed explanation of the methodology used to determine the specific job salaries can be found at *www.salaryexpert.com*).

We also solicited any valid survey data that commenters might be able to submit to us.

The proposed cost per minute for each staff type was derived by dividing the proposed annual salary (converted to 2001 dollars using the Medicare Economic Index) by 2080 to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. To account for the employers' cost of providing fringe benefits, such as sick leave, we used the same benefits multiplier of 1.366 used by Abt Associates.

Comment: We received several supportive comments on our efforts to update the clinical staff salaries used in calculating the practice expense RVUs. Specialty societies representing family physicians and surgeons supported the proposal to reprice clinical staff salaries to approximate current practice

expenses. A specialty society representing rheumatology stated that the repricing of clinical staff salary data represents an overdue positive step toward more accurate refinement of practice expense inputs. A specialty society representing dermatology agreed with the appropriateness of bundling similar clinical staff types into more easily identified and easily tracked clinical labor blended categories.

Response: We agree that using current wage data to price the clinical staff CPEP inputs is one step in ensuring that the practice expense RVUs are based on the resources needed to perform each service. We also would like to express our appreciation to the groups that included salary survey data on various staff types as part of their comments. These additional data have helped us to make appropriate revisions to our original proposals.

The following is a discussion of the specific proposals we made on the pricing of clinical staff types.

• We received no comments on the following proposals. Therefore, they will be implemented as proposed.

• We will price as proposed the staff types physical therapy aide, LPN, RN, certified surgical technician, laboratory technician, cytotechnologist, cardiovascular technician, nuclear medicine technician, optician, respiratory therapist, speech pathologist, audiologist, and counselor.

• We will collapse the medical assistant, technical aide, medical technician, EKG technician, anesthesia technician, technician, and cast technician staff types into a new staff type, ''medical or technical assistant (MTA),'' that will be priced at the medical assistant wage rate of $0.26 per minute.

+ We will bundle the staff type ''RN-cardiology'' into the staff type ''RN.''

+ We will adjust the wage rate for the oncology-certified nurse to be 18 percent higher than the RN.

+ We will bundle the staff type ''surgery assistant'' into the staff type ''certified surgical technician (CST).''

+ We will use the average hourly rate of $15.60 for histologic technologists from the 1998 American Society of Clinical Pathologists' survey to price the histotechnologist staff type.

+ We will use the BLS salary data for electroneurodiagnostic technologists contained in the BLS Occupational Outlook Handbook to price the electrodiagnostic technologist staff type.

+ We will price the wage rate for the EEG technician using survey data from the *Salary Expert.*

+ We will merge the nuclear cardiology technician in with the nuclear medicine technician staff type.

• We were unable to find any national salary data for the electron microscopy technician and, in the absence of such data, proposed crosswalking the salary from the wage rate for the histotechnologist. Though this represented an increase in the per minute cost for this staff type, we stated that we would welcome reliable national survey data from the specialty that we could use in pricing electron microscopy technicians.

Comment: The specialty society representing pathologists recommended that the wage rate for electron microscopy (EM) technician, which we proposed crosswalking from that of the histologic technologist, should more accurately be priced at the same wage rate as the cytotechnologist. The commenter stated that histologic technologists are generally bachelor degree level personnel, whereas EM technicians generally have post-baccalaureate education, parallel to that of a cytotechnologist. In addition, they receive salaries that are higher than general histotechnologists. The commenter also recommended that the title of the EM technician category be changed to EM technologist.

Response: We are persuaded that the commenter has proposed a more suitable crosswalk for this staff type. Therefore, we will crosswalk the wage rate for the EM technologist from that of the cytotechnologist. We will also change the title as suggested by the specialty society.

• We were unable to find any national salary data for registered electroencephalograph technologists (REEGTs) and proposed to maintain the current rate, since the speciality society had recently recommended this rate of pay. However, we also requested reliable national survey data from the specialty that we could use in pricing these three levels of neurodiagnostic staff.

Comment: The American Academy of Neurology (AAN), on behalf of seven related organizations, submitted an abbreviated version of the 2000 American Society of Electroneurodiagnostic Technologists (ASET) Salary Survey. The commenter stated that this national salary survey has been collected triennially by ASET, the main national body representing this allied health professional field, and was not collected for any purpose connected with the physician fee schedule. For office-based registered electroencephalograph technologists, there were 31 responses and a mean salary per hour of $20.11. For all REEGTs, there were 559 responses and a mean salary of $20.53 per hour. The commenters recommend that we substitute either of these salary rates to determine the costs for the REEGT staff type. The specialty society representing sleep medicine requested that we consider the updated salary data that AAN included in its comments on the proposed rule.

Response: We have reviewed this survey and believe that it provides a more appropriate estimate of the wage rate of REEGTs than did our crosswalk to a staff type used in a different specialty. We will use the data for the office-based REEGTS, which results in a wage rate of $0.47 per minute, which we note is not significantly different from our proposed rate for the REEGT staff type.

• We proposed to bundle the vascular technician with the cardiovascular technologist staff type. Currently both are priced at the same rate.

Comment: The American Association for Vascular Surgery, American Society of Neuroimaging, Society of Diagnostic Medical Sonography, Society for Vascular Surgery, and Society of Vascular Technology submitted a joint comment as ''The Coalition.'' The Coalition argued that the BLS was wrong to classify vascular technologists with cardiovascular technologists and technicians because the BLS description of duties for this classification does not include any of the duties performed by a vascular technologist. In addition, the commenters contended that, unlike most cardiovascular technicians, a vascular technologist functions as a direct and largely independent health care practitioner. A skilled vascular technologist undergoes between 2 and 4 years of didactic and clinical post-secondary education as evidenced by the presence of a baccalaureate degree program in vascular technology.

The Coalition recommended that we base the salaries for vascular technologists on data from a survey conducted earlier this year by nVision Research that surveyed by mail 406 randomly selected vascular technologists from a variety of settings. The response rate for this survey was 55 percent. Based on the survey, nVision Research determined that the median annual salary of a vascular technologist is $49,758. A copy of the survey was included with the comment. The commenters also recommended that we change the description of the ''vascular technician'' to ''vascular technologist.'' A specialty society representing echocardiography urged that we adopt the classification of ''vascular

technologist'' as proposed by the above groups.

Response: We agree that the nomenclature of the staff type should be changed to ''vascular technologist.'' We have studied the data provided by the Coalition and have consulted with our medical advisors and now also agree that the salary shown in the submitted survey better represents the current wage rate for vascular technologists. Therefore, we will assign the vascular technologist staff type the recommended yearly salary of $49,758 which results in a per minute wage rate of $0.54.

• We proposed to merge the x-ray technician and radiation technologist staff types, which are currently priced at the same rate, into a staff type called ''Radiologic Technologist.''

Comment: The American Society of Radiologic Technologists (ASRT) submitted with their comment the 2001 ''Radiologic Technologist Wage and Salary Survey'' commissioned by the organization. The comment disagreed with our proposal to merge the x-ray technician and radiation technologist staff types. The society stated that the radiation technologist has completed a formal educational program and has successfully passed a nationally recognized credentialing examination; an x-ray technician denotes a person who is most likely informally trained and who is often employed to perform only very limited x-ray examinations. On the other hand, a society representing therapeutic radiology and oncology recommended that we not crosswalk radiation technologists to ''radiologic technologists and technicians,'' but, instead, change the crosswalk and the name to ''radiation therapist.''

Response: We can understand why the original nomenclature assigned by the CPEP panels to these staff types would be confusing to the commenters. However, it is clear from the imaging services to which the radiation technologist is assigned that this staff type was not considered to be a radiation therapist. In addition, we do not disagree with the distinction made by ASRT between an x-ray technician and a radiation technologist. However, the CPEP panel did not appear to make this same distinction. In fact, the x-ray technician is often assigned to more complex services than the radiation therapist and Abt Associates priced the two staff types at the same wage rate. Therefore, we have made the decision to consider both staff types to be at the same level and to change the title of both to ''radiologic technologist.'' If it is necessary to make a distinction between different levels of radiologic staff, this can be done as part of the refinement process.

Comment: A commenter representing imaging centers recommended that we substitute the ''more accurate and recent salary information'' obtained by the ASRT for the pricing of radiologic technologists. The commenter stated that these data indicate that the mean salary of full-time radiologic technologists is $53,919.

Response: We have reviewed the survey submitted to us by ASRT and have found it to be both comprehensive and useful. We would note that the $53,919 referenced in the comment is the mean salary for all radiologic personnel and includes the salaries of staff level personnel as well as chief technologists and of radiography staff as well as dosimetrists. Therefore, this is not salary information that can be used to price the specific radiology staff types in our database. However, as discussed below, we have used other ASRT data to price certain staff types for which we had no other pricing information. It is interesting to note that the mean salary in the ASRT survey for radiography staff is $36,862, while the 2001 salary rate for the equivalent staff based on the BLS is $37,126; the use of either figure would result in an almost identical per-minute wage rate. This information gives us extra confidence in our proposed wage rate of $0.41 per minute for radiologic technologists, and we will be implementing this salary rate as proposed.

• Because we were unable to find any national survey data regarding the salaries for CAT scan technician, MRI technician, or angiographic technician, we proposed crosswalking these staff types to the BLS radiologic technologist pay scale. We also stated that we would welcome any reliable national survey data that would allow us to separately price these staff types.

Comment: The American Society of Radiologic Technologists (ASRT) recommended that we use the 2001 ASRT survey submitted with its comment to price the MRI, CAT scan and angiographic technologists, rather than crosswalking their wage rate from the radiologic technologist. The ASRT data show an annual salary of $42,143 for a CAT scan technologist and $43,118 for an MRI technologist.

Response: We have reviewed the ASRT data for MRI and CAT scan technologists and will use that data for MRI and CT staff to price these staff types. There is a close congruence between the ASRT and the BLS salaries for those radiologic staff for whom we have data from both sources. Therefore, we have confidence that the wage rate we will use for the CAT scan and MRI technologists will be relatively correct. The wage rate for the CAT scan technologist will be $0.46 per minute and for the MRI technologist $0.47 per minute. We could not find data in the ASRT survey corresponding to the angiographic technician. Therefore, until some reliable national data are available, we will continue to crosswalk this wage rate from that of the radiologic technologist.

• We proposed merging the cardiac sonographer and the ultrasound technician into the sonographer staff type. Currently, all three are priced at the same rate.

Comment: The group of specialty societies commenting as the ''Coalition'' recommended that we maintain the description, ''cardiac sonographer,'' eliminate the description, ''ultrasound technician,'' and change the description ''sonographer'' to ''diagnostic medical sonographer.'' A specialty society representing echocardiography strongly urged that we adopt the above classifications proposed by the Coalition. This commenter also contended that crosswalking the salary for cardiac sonographers from that of diagnostic medical sonographers does not adequately reflect the salaries currently paid to cardiac sonographers. The society is currently seeking a reliable source of current survey information so that we can price cardiac sonographers separately.

Response: We have already proposed eliminating the description ''ultrasound technician'' and will accept the description of ''diagnostic medical sonographer.'' We proposed merging the cardiac sonographer into the sonographer classification because the two staff types were currently priced the same and we did not have any other salary data for the cardiac sonographers. However, we will accept the recommendation to keep the category ''cardiac sonographer'' and would be willing to reconsider the pricing if valid salary data are submitted.

• Because we were unable to find salary information for the staff type ''dosimetrist,'' we proposed crosswalking their salary from that of radiation therapists.

Comment: The American Society of Radiologic Technologists (ASRT) recommended that we review our proposed equal wages rates for radiation therapists and dosimetrists. The commenter reported that the annual salary of $57,330 for staff dosimetrists shown in the submitted 2001 ASRT survey is considerably higher than that for radiation therapists, which reflects their additional educational

requirements. The specialty society representing radiology also opposed combining dosimetrists and radiation therapists in the same group because these two staff types provide very different services for radiation oncology procedures and are paid on different pay scales. This commenter agreed with the proposed increased wage rate for radiation therapists, but believed that the dosimetrists would be paid approximately 20 percent more than their proposed rate. Two other societies, one representing therapeutic radiology and oncology and one representing radiation oncology centers, also supported an increase for dosimetrists and one commenter suggested that we substitute the title ''medical dosimetrist.'' In addition, these two commenters recommended that we use the ASRT data for radiation therapists as well.

Response: We appreciate receiving the ASRT data for dosimetrists and agree that the annual salary suggested by the ASRT survey more accurately reflects the appropriate wage rate for this staff type. The wage rate will be $0.63 per minute. We will also change the title for this staff type to ''medical dosimetrist.'' We will continue to use the BLS data to determine the wage rate for radiation therapists since there has been no evidence presented to show that the BLS survey was in any way not representative.

• We proposed using the average salary data for all certified health physicists from the 1999 survey conducted by the American Academy of Health Physics and the American Board of Health Physics to price the ''physicist'' staff type.

Comment: Three specialty societies representing radiology, therapeutic radiology and oncology, and radiation oncology centers recommended that we use the Professional Information Survey data from The American Association of Physicists in Medicine (AAPM) rather than from the American Academy of Health Physics (AAHP). One commenter pointed out that the AAHP survey does not include physicists working in radiation oncology. The AAPM survey for CY 2000 had an overall response rate of 58 percent and demonstrated an average annual salary of $107,900. One commenter suggested that we also change the title to ''medical physicist.''

Response: No copy of the AAPM survey was included with any of the comments, and we have been unable to review it at this time. However, we would not question the commenters' assertion that the AAPM survey was more relevant to physicists working in radiation oncology than the survey we used to determine our proposed wage rate. Therefore, we are using the AAPM survey salary of $107,900 on an interim basis to price the physicist wage rate and will endeavor to obtain and review this survey to finalize this issue. The wage rate for 2002 will be $1.21 per minute. For clarity, we will also accept the recommendation to change the title to ''medical physicist.''

• We were unable to obtain representative national salary data for the certified ophthalmic technician (COT), the certified ophthalmic medical technologist (COMT), or the orthoptist staff types. We proposed to crosswalk the COT and COMT to the laboratory technician and histotechnician, respectively, since we believe that the skill and responsibility of these staff types would generally correspond. In the absence of any national salary data for the orthoptist, we proposed to crosswalk the salary from that of the COMT, the highest level of ophthalmic medical personnel. We also proposed crosswalking the salary data for the certified retinal angiographer from the data listed for ophthalmic photographers in the *Salary Expert.* We stated that we would welcome reliable and representative national salary data for these staff types.

Comment: The specialty society representing ophthalmologists commented that they would be pleased to offer additional assistance to validate the salaries for ophthalmic medical technicians and other ophthalmic clinical staff. At this time, the commenter agreed that the proposed crosswalks for these staff types are acceptable.

Response: We will be implementing these crosswalks as proposed.

• We proposed to crosswalk the wage rate for the staff type ''dietitian'' from the BLS salary data for dietitians and nutritionists.

Comment: The American Dietetic Association (ADA) commented that it believed that the BLS database includes salaries for non-credentialed dietitians and nutritionists and that we should reference ADA data from its membership surveys that estimates 2001 adjusted median annual income for dietitians to be $51,006.

Response: We would be willing to look at the ADA survey data if they were submitted to us. We would, of course, have to review and analyze these alternative survey data before we could substitute them for the BLS data that we have proposed to use. However, until we are convinced that the ADA data were equally or more representative of dietitians who serve as clinical staff for services on the fee schedule, we will continue to use the BLS data as our source of salary data for dietitians.

• We proposed to delete those clinical staff that can bill separately from the list of CPEP staff types. Therefore, we proposed substituting physical therapy aide for physical therapist, registered nurse for physician assistant, nurse practitioner and psychologist, and counselor for social worker.

Comment: Two specialty societies representing internal medicine and family practice expressed support for this proposal because these staff types, for example, nurse practitioners, are used as physician extenders and their salaries should not be considered as practice expense. A society representing geriatrics argued that we should not delete the clinical staff that can bill separately from the list of CPEP staff types because not all of these individuals bill separately, resulting in a negative impact on geriatrics.

Response: We will implement our proposal to delete clinical staff that can bill independently from our practice expense input database, with the two exceptions noted below. We believe that the costs of these staff types are not practice expenses and should be captured in the work RVUs. This revision to our clinical staff list should not have a negative impact on geriatrics because none of the deleted staff types were assigned to any of the E/M services that would make up a large percentage of geriatricians' case loads.

Comment: A society representing social workers commented that it was not opposed to the deletion from the practice expense inputs of staff types that can bill directly. However, the commenter pointed out that only clinical social workers are able to bill directly, while other social workers cannot. Therefore, the society is opposed to the deletion of the staff type, ''social worker,'' from the CPEP inputs and the substitution of the staff type, ''counselor.'' In addition, the society would at least want the BLS data for ''social worker'' to be used for pricing, though it believes that the BLS data does not differentiate enough between the various types of practice within social work.

Response: The commenter is correct in stating that not all social workers can bill directly. Therefore, we will keep the social worker staff type in our database and will use the BLS data for ''social worker'' to determine the appropriate wage rate. In addition, we will not delete the staff type, ''psychologist,'' which is listed as the clinical staff for the psychological testing services. Because these services have no

physician work RVUs, the work of the psychologist can only be captured through the practice expense RVUs. We can find no appropriate national salary at this time for this staff type. Therefore, we will use the current wage rate of $0.82 per minute.

• We proposed to delete, as redundant, the ophthalmic medical personnel (OMP) staff type and to substitute the COMT/COT/RN/CST blend that was suggested by the American Academy of Ophthalmology and recommended by the PEAC.

Comment: The specialty society representing optometrists agrees with our proposal to delete, as redundant, the ophthalmic medical personnel (OMP) staff type and substitute the COMT/COT/RN/CST staff blend.

Response: We will implement this as proposed. Table 1 lists each staff type remaining in our practice expense input database, the source of the data, the staff type crosswalk used, the proposed annual salary in 2001 dollars, the 2002 wage rate per minute (including benefits) and the current cost per minute (including benefits).

TABLE 1.—REVISED WAGE RATES FOR CPEP STAFF TYPES

Description	Source	Crosswalk	Mean yrly 2001	Hrly + benefits	Revised per minute	Current per minute
Physical Therapy Aide	BLS	Physical Therapist Aides	21,077	13.84	0.23	0.23
Physical Therapy Assistant	BLS	Physical Therapist Assistants	35,223	23.13	0.39	N/A
Medical or Technical Assistant	BLS	Medical Assistants	23,681	15.55	0.26	0.16
LPN	BLS	Licensed Practical Nurses	30,341	19.93	0.33	0.27
RN	BLS	Registered Nurses	46,494	30.53	0.51	0.42
RN Oncology	BLS	Registered Nurses plus adjustment	54,862	36.03	0.60	0.50
Certified Surgical Technician	BLS	Surgical Technologists	28,814	18.92	0.32	0.26
Lab Technician	BLS	Medical and Clinical Laboratory Technicians.	29,724	19.52	0.33	0.29
Histotechnologist	ASCP	Histologic Technologist	33,925	22.28	0.37	0.31
Electron Microscopy Technologist	X–WALK	Cytotechnologist	41,099	26.99	0.45	0.31
Cytotechnologist	BLS	Medical and Clinical Laboratory Technologists.	41,099	26.99	0.45	0.42
EEG Technician	Salary Expert	Electroencephalographic Technician	29,151	19.14	0.32	0.28
Electrodiagnostic Technologist	BLS	Electroneurodiagnostic Technologists	33,529	22.02	0.37	0.30
Registered EEG Technologist	ASET	Registered EEG Technologist	42,707	28.05	0.47	0.40
Vascular Technologist	nVision Survey	Vascular Technologist	49,758	32.68	0.54	0.35
Cardiovascular Technician	BLS	Cardiovascular Technologists and Technicians.	34,794	22.85	0.38	0.35
Radiologic Technologist	BLS	Radiologic Technologists and Technicians.	37,126	24.38	0.41	0.32
Mammography Technologist	ASRT	Mammography Technologist	39,212	25.75	0.43	N/A
Angiographic Technician	BLS	Radiologic Technologists and Technicians.	37,126	24.38	0.41	0.35
CAT Scan Technologist	ASRT	Computed Tomography Technologist	42,143	27.68	0.46	0.32
MRI Technologist	ASRT	Magnetic Resonance Imaging Technologist.	43,118	28.32	0.47	0.32
Nuclear Medicine Technician	BLS	Nuclear Medicine Technologists	44,361	29.13	0.49	0.39
Diagnostic Medical Sonographer	BLS	Diagnostic Medical Sonographers	45,751	30.05	0.50	0.39
Cardiac Sonographer	BLS	Diagnostic Medical Sonographers	45,751	30.05	0.50	0.39
Radiation Technical Therapist	BLS	Radiation Therapists	45,333	29.77	0.50	0.40
Medical Dosimetrist	ASRT	Medical Dosimetrist	57,330	37.65	0.63	0.50
Medical Physicist	AAPM	Medical Physicist	110,166	72.35	1.21	0.97
COT	X–WALK	Lab Technician	29,724	19.52	0.33	0.26
COMT	X–WALK	Histotechnician	33,925	22.28	0.37	0.28
Optician	BLS	Opticians, Dispensing	26,336	17.30	0.29	0.28
Certified Retinal Angiographer	Salary Expert	Ophthalmic Photographer	35,453	23.28	0.39	0.35
Orthoptist	X–WALK	COMT	33,925	22.28	0.37	0.32
Respiratory Therapist	BLS	Respiratory Therapists	38,537	25.31	0.42	0.42
Speech Pathologist	BLS	Speech-Language Pathologists	49,996	32.83	0.55	0.42
Audiologist	BLS	Audiologists	47,748	31.36	0.52	0.41
Registered Dietician	BLS	Dieticians and Nutritionists	39,050	25.65	0.43	0.37
Counselor	BLS	Mental Health Counselors	30,769	20.21	0.34	0.42
Social Worker	BLS	Medical and Public Health Social Workers.	37,011	24.31	0.41	0.33

The CPEP clinical staff inputs also include blends of staff types that are used for those services when more than one type of clinical staff may be used in the performance of the service. We will establish the payment rates for these blends by calculating a simple average of the wage rates of the staff types included. Table 2 shows the blended staff types, the 2002 cost per minute and the current cost per minute.

Note: We received no comments on the proposed cost per minute for the staff blends, so these rates will be implemented as proposed.

TABLE 2.—REVISED WAGE RATES FOR CPEP BLENDED CLINICAL STAFF TYPES

Description	Revised per minute	Current per minute
COMT/COT/RN/CST	0.38	0.307

TABLE 2.—REVISED WAGE RATES FOR CPEP BLENDED CLINICAL STAFF TYPES—Continued

Description	Revised per minute	Current per minute
Lab Tech/Histotech	0.35	0.297
Lab Tech/MTA	0.30	0.257
Optician/COMT	0.33	0.278
RN/LPN	0.42	0.389
RN/LPN/MTA	0.37	0.317
RN/OCN	0.56	0.497
RN/Respiratory Therapist	0.47	0.421
RN/Sonographer	0.51	0.405
Dosimetrist/Physicist	0.920	N/A

(v) Revision of the Ophthalmology Visit Supply Package

In its May 2000 submission to us, the RUC recommended the use of an ophthalmology visit supply package that would contain the routine supplies typically used in each 90-day global postsurgical visit for ophthalmology services. We accepted this recommendation. However, upon further review, we noted that two of the supplies, rev eyes and post myd spectacles, were not used in many of the postsurgical office visits. Therefore, after consulting with the ophthalmology specialty society, we proposed to remove these two items from the ophthalmology visit package. Instead, we proposed including these items as appropriate on a code-by-code basis.

Note: Since we received no comments on this issue, we will implement this revision on the supply package as proposed.

(vi) Deletion of Contrast Agents from the Practice Expense Inputs

Section 430(b) of BIPA amends section 1861(t)(1) of the Act to include contrast agents in the definition of drugs and biologicals. Previously, contrast agents were defined as supplies and were included in the list of CPEP supplies for the appropriate services. Therefore, we proposed to delete the costs of the following contrast agents from our CPEP data: hypaque, methylene blue, high-density barium, polibar, telopaque tablets, barium paste contrast, effervescent sparkies (fizzies), and renographin-60 iodinated contrast.

Comment: The specialty society representing radiology had no comment on the suggested list of deletions from the CPEP supplies. However, the society expressed concern that there are no HCPCS codes established for these deleted items and wanted information on how to bill for these supplies.

Response: As stated above, we proposed to delete contrast agents from the practice expense inputs in response to legislation that included contrast agents in the definition of drugs. This proposal was made to ensure that we did not include in the practice expense the costs of items that could also be billed separately. However, section 1842(o)(1) of the Act makes clear that the payment of 95 percent of the average wholesale price (AWP) can be made only if the drug is not paid on a cost or prospective payment basis. We believe that if we do include payment for any contrast agent in the practice expense RVUs, no other payment should be made for this item. After further consideration of this issue, however, we will continue to include the contrast agents listed in our proposal in our practice expense inputs at this time. Therefore, we are withdrawing the proposal.

c. Physician Time

RUC Time Database

The primary sources for the physician time data used in creating the specialty-specific practice expense pools are the surveys performed for the initial establishment of the work RVUs and the surveys submitted to the AMA RUC. The AMA informed us that some of the times used for the November 1998 final rule (63 FR 58823) differed from the official RUC database, and we agreed to use the RUC-verified physician time database when we received it from the AMA. Subsequently, the AMA notified us that there were gaps in its own database for certain global surgery codes and that a revised time database would be sent to us once all the times were verified. We have now received this revised database and proposed to use it in the calculation of the specialty-specific practice expense pools. It should be noted that the RUC database reflects the physician times for those codes that were surveyed as part of the second 5-year review of physician work.

Comment: We received a number of comments that supported using the physician time data. One commenter indicated that the new time database is expected to provide greater accuracy and consistency in the practice expense calculations. While commenters representing family physicians, internists, and rheumatologists supported use of the new time data, they also indicated that improvement is still needed. Specifically, these commenters suggested that the number and level of postoperative visits and the corresponding physician time included in the global surgical period may be overstated. The commenters noted that we previously indicated that we would study length of stay data relative to the number of postoperative visits and included in the surgical period, and they encouraged us to use this information to further refine the physician time data. One commenter indicated that surgeons rarely meet the criteria for billing critical care services in the postoperative period even though the time and value of critical care services are proposed for inclusion in the global period of some surgical codes.

Organizations representing thoracic surgeons indicated that we should not incorporate the new time data that will result in additional practice expense reductions for thoracic and cardiac surgery. These commenters said that no further reductions in the practice expense RVUs for cardiac surgery should be made until new studies of practice expense related issues by the Office of Inspector General and the General Accounting Office are completed. This commenter indicated that the new physician time data covers only 585 of the 7,928 codes in the physician fee schedule but directly affects cardiothoracic surgery because there are revised times for many high volume heart and chest procedures. The commenter suggested that the new time information needs to be put in the context of changes in physician time that may have occurred in the last five to ten years on the remaining 7,343 procedure codes where there are no new physician times. Another commenter representing a cardiology subspecialty indicated that we incorporated RUC time data for only 1,900 of the more than 7,000 procedure codes. This commenter suggested that we should continue using available time from a single source until a consistent source that includes information on all CPT codes is available.

Response: As indicated in the proposed rule, the RUC submitted physician time data for nearly 2,000 CPT codes in May 2001 and recommended that we use these new physician times in the practice expense methodology. The RUC recently sent new time for use in the final rule that reflected refinements for a few codes. We note that the source of the RUC times are actually the physician specialty societies themselves, including those associations that have objected to our use of the data. The data largely come from the specialty society surveys that were forwarded to the RUC to support requests for physician work RVUs for new and revised codes or services that were part of the 5-year review. The RUC made a comprehensive effort to validate these times before forwarding them to us. The RUC indicated to us that, over a period of 2

years, specialties had been provided with an opportunity to review the data and determine that they were accurately recorded.

While the new times forwarded by the RUC represent a minority of CPT procedure codes, we note that they account for over 60 percent of the allowed services that are paid under the physician fee schedule. In response to the comment that we should make changes only when we have a single source of time data for all codes, we note that there has never been a single source of time for all codes. While time for some codes is based on the original work of Harvard University, there are many codes that came into existence since the Harvard survey was completed. The only data source for these codes is the RUC.

We acknowledge that the Office of Inspector General is studying issues related to physicians bringing clinical staff to the hospital and the General Accounting Office is reviewing our use of supplemental practice expense survey data. Since these studies are unrelated to physician time, we do not believe they constitute a reason to suspend incorporation of the new time data into the practice expense methodology.

In response to the comments that suggest that the physician times in the postoperative period may be overstated, the RUC indicated to us that ''a number of improvements were made to the specifications regarding the level of postoperative visits to more accurately capture each element of physician time.'' While the total times we received from the RUC reflect the number, types, and level of E/M services furnished in the postoperative surgical period, these services are not separately paid when furnished as part of a global surgical service. Since these services are not paid separately, it is difficult to find objective information that indicates how E/M services are provided in the postoperative period. Currently, the only source of information we can use is information that the RUC has supplied and data that previously existed in our files. While we have undertaken research that combines information on inpatient hospital stays with claims for physicians' services, these data have limitations for determining the level or type of visit being furnished in the postoperative period. We would consider any further evaluation by the RUC on this issue.

d. Calculation of Practice Expense—Other Issues

Comment: Several commenters requested additional clarification and information concerning the cause of reductions of 9 to 13 percent in the practice expense RVUs for electrophysiology services. One commenter indicated that there was no explanation of the proposed reduction in practice expense for CPT codes 33207, 33208, 33249, and 93651. The commenter suggested that we should provide a more complete explanation of the proposed reductions or rescind them.

Response: Our observation is that there is no more than a 9 percent reduction in practice expense RVUs for any of these codes. We also note that the change in total payment for these codes as a result of the change in practice expense RVUs is less than half of this amount. We modeled five different changes to the practice expense methodology in our August 2, 2001 proposed rule (66 FR 40397). Of these changes, the change to physician time has the greatest effect on these codes. Since the change in the practice expense RVUs results from new information that affects payments for all procedure codes, we are continuing to implement the reduction in practice expense RVUs that were proposed for these codes.

Comment: We received one comment expressing concern that the separate professional interpretation and technical components for CPT code 95824 (cerebral death evaluation) have been eliminated. The commenter requested that we restore the professional and technical components of this service and crosswalk the technical component value from a similar code, CPT code 95822 (EEG, sleep only). The commenter also suggested that the work RVUs should be 1.08 RVUs, the same as similar EEG codes.

Response: We have restored the separate professional and technical components of this service. This service will likely be exclusively furnished for patients who are in an institutional setting. Thus, we will pay under the physician fee schedule only for the professional interpretation. Payment for the technical component of the service will be made through our payment to the institution for facility services. Since the technical component of this service is never provided outside of a hospital, we do not have enough information under the resource-based methodology to establish nonfacility pricing. In the unlikely event that this service is provided in the nonfacility setting, we are making the global and technical component of this service subject to carrier pricing. This change will apply to several other services that are not furnished in nonfacility settings. We are not making changes to the physician work RVUs for cerebral death evaluation in this final rule. There were no requests to revise the work RVUs for this code as part of the 5-year review of physician work.

Comment: An organization representing vascular surgeons stated that the methodology used to incorporate the supplemental practice expense survey data has failed. This commenter indicated that the practice expense per hour for vascular surgeons increased by 9 percent from using supplemental data; however, payments actually declined between the November 2000 final rule and the August 2001 proposed rule. The commenter provided potential explanations for the change to practice expense RVUs. The commenter suggested that the results are inconsistent with the statute that requires payments to recognize all costs and violates the Administrative Procedure Act that rulemaking cannot be arbitrary and capricious.

The commenter suggested an option that would result in a total increase in vascular surgery payments of 9 percent, consistent with the results of the supplemental survey. This option would involve identifying vascular surgery procedure codes that decreased in payment and reallocating RVUs such that aggregate payments to vascular surgeons would increase by 9 percent.

Response: While the commenter is correct in stating that the practice RVUs for several high-volume vascular surgery procedures declined in our proposed rule, it is important to note that the changes occurred independent of the use of supplemental practice expense survey data. The supplemental practice expense survey data were incorporated into the methodology in the November 1, 2000 final rule (65 FR 65385).

The changes that occurred between the November 2000 final rule and the August 2001 proposed rule were the result of the five changes to the methodology that we modeled and described in the August 2, 2001 (66 FR 40397) proposed rule. The additional reductions in practice expense payments for vascular surgery codes that concern this commenter are attributed to the changes we made to physician time. As we have stated previously, the explanation of how time affects specific codes is complex and requires extensive data analysis. We would be willing to meet with interested parties to discuss the effects of the practice expense methodology further.

The commenter suggests that we make decisions about an appropriate increase

in value for specific services and reallocate RVUs consistent with these decisions. We do not believe that such a policy would be appropriate. We have established a methodology for determining practice expenses and have valued all services using that process with the exception of services that have no physician work RVUs. For these services, we have established RVUs using an alternative methodology. It is not possible to deviate from those methodologies and reallocate RVUs to achieve particular results that may be more desirable to some individuals than to others. Such decisions about ''appropriateness'' would become highly subjective and would, in our view, be more likely to be criticized as arbitrary and capricious.

Comment: We received comments from specialty societies representing technical component providers regarding the status of the zero-work pool. Commenters representing radiology, cardiology, echocardiography and radiation oncology centers strongly supported our position of maintaining the status of the zero-work pool until an appropriate alternative methodology can be determined. Two commenters argued that none of the direct or indirect cost information resulting from the CPEP process should be utilized to establish payment amounts for technical component services unless and until we further consider the entire methodology to be applied for technical component services. All commenters urged us to consult closely with associations representing the zero-work pool providers before making any changes in this regard. One commenter emphasized that no changes should be made without further research and discussion.

Response: We agree that the status of the zero-work pool should not be changed until an alternate approach that values technical component services appropriately can be developed. Over the next several months, we will be analyzing the options for such an alternative approach contained in the report, ''The Resource-Based Practice Expense Methodology: An Analysis of Selected Topics,'' prepared by our contractor, The Lewin Group. This report can be found on our web site, and we would welcome comments on these options from all interested parties. (See the Supplementary Information section of this rule for directions on accessing our web site.) We also agree with the commenters that we should consult with the affected specialties as we proceed, and we will seek to maintain an open dialogue with the medical community on this issue.

Comment: A commenter representing speech, language, and hearing professionals recommended that the zero-work pool be modified to accept the clinical staff wage increases. Seventy percent of the procedure codes used by audiologists that are covered by Medicare are in that pool and, thus, even though the proposed wage rate for audiologist has increased by 24 percent, this increase will not be reflected for those non-work services.

Response: The commenter is correct in stating that, because the CPEP data are not used as allocators in the zero-work pool, the increases in the clinical staff wage rates will not affect the payments for audiology services at this time. However, as we mentioned above, we are seeking to develop an appropriate alternative for the zero-work pool and, when such an alternative is implemented, the revised wage rates will be applied to audiology services. In addition, we allow specialties to withdraw their services from the zero-work pool if the specialty believes that their services will be more appropriately valued outside that pool.

Comment: An organization representing diagnostic imaging centers stated that, if we adopt the suggestion in the report of The Lewin Group to establish specialty-specific zero-work pools, it has already conducted a survey that establishes the costs per hour of providing diagnostic imaging technical component services. The commenter added that, regardless of the approach that we choose, the organization welcomes the opportunity to work with us with respect to any changes that may be contemplated in the zero-work pool methodology.

Response: As we have noted above in our discussion on specialty-specific supplementary surveys, all of these surveys must meet the criteria stated in our November 2000 final rule. We would be willing to review the survey to see if the data can be used to develop a specialty-specific practice expense per hour. In addition, we, too, would welcome the opportunity to work with the organization as we develop an alternative to the zero-work methodology.

e. Site-of-Service

Comments on Site-of-Service Clarification of Payment Policy

In the November 2, 1998 final rule (63 FR 58830) and the November 2, 1999 final rule (64 FR 59407), we indicated the circumstances under which either the facility or the nonfacility RVUs are used to calculate payment for a service. Specifically, we indicated that the lower facility practice expense RVUs apply when the service is performed in an Ambulatory Surgical Center (ASC) and the procedure is on the ASC-approved procedures list. The higher nonfacility practice expense RVUs apply to procedures performed in an ASC that are not on the ASC-approved list because there will be no separate facility payment for these services. As explained in the August 2001 proposed rule, we have received a number of inquiries about the place-of-service that should be used on the Medicare claim when a service that is not on the ASC-approved procedures list is furnished in an ASC. In these circumstances, we stated that physicians should indicate ASC as the place-of-service on the Medicare claim. Other questions have arisen as to whether a beneficiary can be billed for the ASC facility fee when Medicare does not pay a facility fee because a procedure not on the ASC list is performed in a certified ASC. In this situation, Medicare pays the physician the higher nonfacility practice expense RVUs because the ASC is effectively serving as a physician's office, and Medicare's payment for the physician's service includes payment for all practice expenses incurred in furnishing the service. The ASC benefit is not implicated since the services do not meet the provisions of section 1833(i) of the Act. The services are covered as physicians' services and paid under the physician fee schedule. Therefore, payment to the physician reflects payment for the whole service, and the beneficiary cannot be charged in excess of the limiting charge for the physician fee schedule service.

Comment: Two commenters indicated that conditions of participation and/or survey and certification guidelines limit physicians in an ASC to furnishing only surgical procedures on the ASC approved list of procedures. They stated that such restrictions interfere with providing medical care that is in the patient's interest. The commenters request that we revise the regulations to allow physicians to furnish surgical and other medical procedures that are not on the approved ASC list in an ASC.

Response: Because our proposal relates only to payment policy, we are finalizing it as proposed. The payment policy will apply to services furnished in an ASC that are not on the ASC-approved list to the extent that such services are permitted under the conditions of participation developed by our Office of Clinical Standards and Quality (OCSQ) and by the survey rules developed by our Center for Medicaid and State Operations (CMSO). It is our understanding that current regulations

that restrict ASCs to furnishing surgical services does not limit them to surgical services on the ASC-approved list, but rather, includes all surgical services. However, questions about rules that limit services that can be furnished in an ASC are beyond the scope of this final rule.

B. Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists Performing Screening Sigmoidoscopies

Based on our review of current medical literature, we believe that nurse practitioners (NPs), clinical nurse specialists (CNSs), and physician assistants (PAs) whose services are covered under Medicare and who have been trained are qualified to perform screening sigmoidoscopies safely and accurately. Therefore, in the August 2, 2001 proposed rule, we proposed revising § 410.37(d) to provide that, in order for screening sigmoidoscopies to be covered, they must be performed by medical doctors, doctors of osteopathy, PAs, NPs, and CNSs, if they meet the applicable Medicare qualification requirements in §§ 410.74, 410.75, and 410.76, and if they are authorized to perform these services under State law.

Comment: Fifteen commenters addressed the issue of whether to allow non-physician health care professionals to perform screening flexible sigmoidoscopies for Medicare coverage and payment purposes. Four of the commenters representing national non-physician health care professional organizations and a health care consultant group enthusiastically supported the proposal. Ten commenters, all national medical associations or medical specialty groups, expressed various concerns about the proposal but agreed that it was appropriate for NPs, PAs, and CNSs to perform these services. These commenters suggested clarification and revision of the rule in a number of different areas, such as the need for physician supervision and appropriate training and experience standards, to ensure quality of care in the non-physician performance of these examinations. Two of these ten commenters that suggested the need for additional requirements were national gastroenterological physician groups which were divided in their enthusiasm for the proposal. The American Gastroenterological Association indicated that properly trained physician assistants, nurse practitioners and clinical nurse specialists are capable and qualified to perform screening flexible sigmoidoscopies. However, the Association insisted that in no case should such practitioners be permitted to do so without being directly supervised by an appropriately trained and qualified onsite physician. In addition, the Association urged that these non-physician providers should never be allowed to perform these examinations without some assurance that they have been properly educated and trained to perform them. These comments were echoed by several other physician groups. On the other hand, the American College of Gastroenterologists supported the proposal without specifically mentioning the need for physician supervision and education and experience requirements. The College emphasized that there is a great need for sigmoidoscopy screening to be performed in the Medicare age group. Moreover, they observed that there may not be sufficient numbers of physicians available to perform the procedure, posing an access problem for our beneficiaries. The College stated that, if we proceed with the proposal, non-physician practitioners should be required to provide certain specific information to beneficiaries stating who had performed the examination and its impact on available benefits in future years.

Another organization representing family physicians also noted conditions which should be met if these practitioners provide this service as proposed, but indicated that the existing Medicare regulations for these practitioners suggested that these conditions are met. For example, existing Medicare regulations require general (not onsite) rather than direct (onsite) supervision of PAs. Several other physician organizations in their recommendations also appear to support a requirement less strict than direct physician supervision.

One other commenter—a national medical association—opposed the proposal because of concerns as to whether non-physician health care professionals could respond appropriately to problems or complications that might possibly occur during the performance of the screening procedure when a physician (with a higher level of medical skills) is not present at the facility. None of the commenters who suggested revisions to the proposed rule to specify requirements for physician supervision and/or formal training and experience, or who opposed it, produced scientific evidence in support of their views.

Response: As we indicated in the proposed rule, a growing body of evidence from the medical literature has shown that certain properly trained non-physician health care professionals can carry out screening by flexible sigmoidoscopy as accurately and safely as physicians. (Scheon et al. Archives of Internal Medicine 2000) This procedure requires fewer supervised examinations to attain objective measures of technical competency than other endoscopic procedures, does not require sedation, and has a low rate of related complications. In the studies reviewed, physician and non-physician endoscopists achieved similar polyp detection rates and depth of insertion in screening performed independently. No significant complications from sigmoidoscopy were reported in any of these studies. The level of satisfaction with the procedure was similar for all practitioners.

This demonstration of the ability of non-physician practitioners to perform flexible sigmoidoscopy screening safely and accurately is a very significant development. As the American College of Gastroenterology noted in its comments, there is a physician availability and a related beneficiary access problem of concern to CMS. The Balanced Budget Act of 1997, effective January 1, 1998, expanded Medicare coverage of non-physician practitioner services to address concerns about access to services, especially in rural and other areas of the United States where there is a lack of availability of physicians for performing certain services such as screening flexible sigmoidoscopies. The law and related regulations also outline the level of supervision or medical direction for these non-physician practitioners.

Flexible sigmoidoscopy is one of the promising modalities available for decreasing mortality from colorectal cancer. The American Cancer Society estimates that more than 56,000 Americans will die of colorectal cancer this year. Studies have found that the use of screening flexible sigmoidoscopy could lead to a 30 percent reduction in total colorectal cancer mortality. (Selby et al. New England Journal of Medicine 1992.) In view of limited Medicare beneficiary access in certain areas, because screening flexible sigmoidoscopy remains an underused cancer-prevention procedure, and, in the absence of any submitted scientific literature that contradicts the underlying medical evidence supporting the proposal, we do not believe that commenters have presented us with a basis for revising the proposal as they have suggested. However, we have found that a number of commenters have offered us interesting suggestions for implementing the proposal and clarifying the agency's intent in this

regard, which we explain in our response to the more specific comments summarized below.

Comment: Several commenters referenced a recent OIG report entitled ''Medicare Coverage of Non-Physician Practitioner Services'' (OEI–02–00–00290), which they believe makes clear that CMS does not have systems in place to ensure that non-physician practitioners who provide beneficiaries with medical services and who bill Medicare directly, are performing their services in accordance with State law. One commenter states that the report implies that it is not possible for Medicare to ensure that a State law allows non-physician practitioners to provide flexible sigmoidoscopies or that the services are provided in an integrated practice arrangement with appropriate physician supervision. For example, the commenter pointed out that 16 carrier medical directors interviewed by the OIG reported that they do not verify that non-physician practitioners are performing services within their State scope of practice, and at least 22 carriers do not check the collaborative agreement required for nurse practitioners and clinical nurse specialists. The commenter indicated that the OIG concluded that services performed and billed by non-physician practitioners create potential payment and quality of care vulnerabilities since, (1) ''non-physician practitioner billings are rising rapidly, but controls, which are based on scopes of practice, are limited'', and (2) carriers ''do not have sufficient guidance to distinguish which non-physician practitioner services should be reimbursed by the program and which should not.'' In light of these OIG findings, the commenter urges CMS to review whether and how the agency and its carriers can ensure that the above-mentioned concerns are resolved successfully when non-physician practitioners perform screening flexible sigmoidoscopies. The commenter says that ''it is vital that CMS takes steps to ensure the fulfillment of these requirements to minimize any risk of experiencing the vulnerabilities referenced in the OIG report with respect to quality and payment issues.''

Response: We agree with OIG's conclusion identifying program vulnerabilities when non-physician practitioners bill Medicare directly for their services. We also respect beneficiaries' choices and their need for access to medical services. While appreciative of OIG's suggestion that it may be appropriate to consider additional controls for Medicare payments to non-physician practitioners, we are sensitive to issues that might arise from different treatment of different classes of practitioners. As appropriate, we will monitor non-physician practitioner services for both overall trends and for complex services.

Medicare currently defers to State licensing boards for regulating and enforcing scope of practice laws. Before issuing a Medicare billing number to a nurse practitioner or a nurse clinical specialist, contractors first determine whether the applicant has a valid license within the State. If a licensing board subsequently acts to suspend a practitioner's license to practice, then Medicare suspends payments under the practitioner's Medicare billing number. This practice is the same for physician and non-physician practitioners.

To protect the integrity of the Medicare program, all claims submitted are subject to data analysis that may lead to a focused or a random review by a Medicare contractor. If Medicare is to begin monitoring practitioners for compliance with State laws and regulations, the program will have to develop additional regulations and policies and impose additional workloads on contractors and perhaps for all practitioners as well. In deciding whether such a process is necessary and appropriate, we will carefully consider these comments in this regard.

Comment: One commenter asked CMS, in implementing the proposal, to ensure that non-physician practitioners are required to tender a standard notification to Medicare beneficiaries providing them with a clear statement that the screening flexible sigmoidoscopy is being furnished by a non-physician practitioner. In addition, the commenter suggests that the beneficiary be notified that under the new colorectal cancer screening benefit, effective July 1, 2001, any average-risk individual receiving a covered screening flexible sigmoidoscopy will be precluded by law from receiving Medicare payment for a screening colonoscopy (which under Medicare regulations (§ 410.37(f) must be furnished by a physician)) for four years.

Response: We believe that our Medicare beneficiaries generally are knowledgeable about the identity of the Medicare practitioner that is furnishing them with a flexible sigmoidoscopy screening examination. Accordingly, we believe that there is no need for non-physician practitioners to provide beneficiaries with any formal notification statement in this regard. As for the suggestion that a non-physician practitioner should notify an average-risk beneficiary that providing him/her with a screening flexible sigmoidoscopy will preclude Medicare from paying for a screening colonoscopy (which must be performed by a physician) for four years, we believe that all Medicare practitioners should help to inform beneficiaries with respect to this limitation. However, we do not believe that any practitioner should be required to formally notify beneficiaries to this effect. While we believe that our Medicare contractors, and all our practitioners have an important role to play in educating our beneficiaries about the various conditions of coverage and payment limitations that apply to different colorectal cancer screening options that are available to them, we will not use these regulations as a mechanism for implementing the requested educational efforts.

Comment: One commenter suggested that we allow registered nurses to perform these as well, as a delegated act, under a physician's direction with the physician billing Medicare for the procedure.

Response: The regulation proposal to allow nurse practitioners, physician assistants, and clinical nurse specialists to perform screening flexible sigmoidoscopies for Medicare purposes was designed to increase beneficiary access to these screening services, especially in rural and other areas where there is a shortage or a lack of availability of physicians who are trained and qualified to perform these examinations. These non-physician practitioners are typically licensed independent practitioners who are recognized under the Medicare law and regulations for coverage and payment purposes. Under Medicare, these non-physician practitioners may be paid under the physician fee schedule for their tests (and treatments) that would be physicians' services if furnished by a physician when they are authorized by the State to perform such services. Registered nurses are not licensed independent practitioners who are recognized under Medicare law for coverage and payment purposes.

Comment: One commenter suggested that we should monitor beneficiary health outcomes that result from the performance of sigmoidoscopy examinations by non-physician practitioners to ensure that they are done safely and accurately.

Response: We had not planned to monitor beneficiary outcomes that might be related to implementation of the proposal to allow non-physician practitioners to perform flexible sigmoidoscopy screening because of the available evidence that they can provide these services safely and effectively. If we were to consider doing this,

however, we would probably want to consider doing a comparative study of health outcomes of beneficiaries who have been screened by both physician and non-physician practitioners who have performed these examinations.

Such a study would mean that a number of physician and non-physician practitioners would have to collect and report data to us on their Medicare patients for a certain period of time, which could be burdensome for them. We may be interested in doing a study in this area in the future if we had any credible evidence of a serious problem in this area, but, at this time, we do not believe a study is necessary.

Result of Evaluation of Comments

We are adopting our proposal to allow certain non-physician practitioners to perform screening flexible sigmoidoscopies.

C. Services and Supplies Incident to a Physician's Professional Services: Conditions

Section 1861(s)(2)(A) of the Act authorizes coverage of services and supplies (including drugs and biologicals that are not usually self-administered by the patient) furnished incident to a physician's service. These drugs and biologicals are commonly furnished in physicians' offices without charge or included in the physicians' bills. This statutory ''incident to'' benefit differs from the ''incident to'' benefit in the hospital setting as set forth in section 1861(s)(2)(B) of the Act, which authorizes coverage of hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to a physician's service furnished to outpatients and partial hospitalization services furnished to outpatients incident to a physician's service. This provision only addresses coverage of ''incident to'' services under section 1861(s)(2)(A) of the Act. In addition, the statute provides Medicare coverage of services incident to practitioners other than physicians.

The Medicare Carriers Manual currently requires that the physician (or other practitioner) be either the employer of the auxiliary personnel or be an employee of the same entity that employs the auxiliary personnel. In the August 2, 2001 rule, we proposed to revise § 410.26 to codify our existing policy outlined in section 2050 of the manual. Specifically, we proposed to codify the definitions of auxiliary personnel, direct supervision, independent contractor, leased employment, non-institutional setting, practitioner, and services and supplies for purposes of services provided incident to a physician's service.

In addition, we proposed to allow auxiliary personnel to provide services incident to the services of physicians (or other practitioners) who supervise them, regardless of the employment relationship of the physician (or other practitioner) to the entity that employed the auxiliary personnel.

All commenters supported the proposal. Their specific comments are addressed below.

Comment: Commenters noted three errors in the proposed text of the regulation. First, in the definition of auxiliary personnel set forth in § 410.26(a)(1), after the phrase ''under the supervision of a physician,'' the term ''(or other practitioner)'' was omitted. Second, in the definition of services and supplies set forth in § 410.26(a)(7), the phrase ''(including drugs and biologicals that, as determined in accordance with regulations, cannot be self-administered)'' should be changed to ''(including drugs and biologicals which are not usually self-administered by the patient)'' in accordance with section 112 of the BIPA, which amended sections 1861(s)(2)(A) and (B) of the Act. Third, in the supervision requirement set forth in § 410.26(b)(5), the word ''direct'' was omitted.

Response: We agree with these comments, and we have corrected these errors.

Comment: One commenter requested that independent contractor physicians also be recognized as employees under the reassignment policy set forth in section 3060 of the Medicare Carrier Manual.

Response: As stated in the August 2, 2001 rule, this proposal only applies to the incident to policy. Furthermore, we are not defining or re-defining the term employment. Instead, we proposed to permit physicians (or other practitioners) to directly supervise auxiliary personnel regardless of the employment relationship of the physicians (or other practitioners) with the entity that hired the auxiliary personnel. In order to bill and receive payment from Medicare under this policy, all other applicable requirements must also be met. For example, the service must be medically reasonable and necessary, and appropriate reassignment must be executed.

Comment: One commenter suggested using in § 410.26(b) all of the terms defined in § 410.26(a) or deleting the terms not used in § 410.26(b).

Response: We found one term—leased employment—that was not used in § 410.26(b). However, we will not eliminate this term because it is used to define the term auxiliary personnel.

Comment: Several commenters requested that we clarify and distinguish between the physician (or other practitioner) ordering the incident to service and the physician (or other practitioner) supervising the auxiliary personnel who perform the incident to service. They stated that confusion exists as to whose Medicare Part B billing number should be used on the claim form.

Response: Inherent in the definition of an incident to service is the requirement that the incident to service be furnished incident to a professional service of a physician (or other practitioner). When a claim is submitted to Medicare under the billing number of a physician (or other practitioner) for an incident to service, the physician is stating that he or she either performed the service or directly supervised the auxiliary personnel performing the service. Accordingly, the Medicare billing number of the ordering physician (or other practitioner) should not be used if that person did not directly supervise the auxiliary personnel. We added language to the supervision requirement set forth in § 410.26(b)(5) to reflect this clarification.

Comment: One commenter pointed out that the claim form currently requires the physician (or other practitioner) to certify that he or she personally supervised the employee. Therefore, the commenter requested that we update the claim form to reflect the proposed regulations.

Response: We plan to update not only the claim form but also section 2050 of the Medicare Carriers Manual to reflect the new regulations.

Comment: A few commenters noted that the individual does not always receive an IRS–1099 form under an independent contractor arrangement. Instead, when a clinic, for example, contracts with an entity that has hired individuals to be furnished to the clinic, then the entity (and not the individual) receives the IRS–1099 form.

Response: We agree with these commenters. Therefore, we have added language to the definition of an independent contractor set forth in § 410.26(a)(3) to reflect this practice. However, we again emphasize that the applicable reassignment rules must also be met and that this incident to policy does not in any way alter the current requirements for valid reassignment.

Comment: One commenter encouraged us to specify in the regulations the acceptability of forms (other than the IRS W–2 form) that the Internal Revenue Service recognizes as

proof of employment, such as the Payroll Agent arrangement where IRS forms 2678 and 1997C are used instead.

Response: Under our proposal, the employment relationship is irrelevant to whether a physician (or other practitioner) can effectively furnish direct supervision of the auxiliary staff. Therefore, we decline to include language that may define or re-define the term employment.

Comment: One commenter suggested that we also include Ambulatory Surgical Centers (ASCs) and Community Mental Health Clinics (CMHCs) in the definition of a non-institutional setting because Medicare Part B payments for services provided in these settings are paid through the facility relative value units (RVUs) rather than the non-facility RVUs.

Response: The definition of a non-institutional setting is not derived from the definition of a facility used to determine the site of service and the application of the facility or non-facility RVUs. Because section 1861(s)(2)(B) of the Act authorizes payment for hospital incident to services, section 1861(s)(2)(A) of the Act cannot authorize payment for hospital incident to services. This provision is reiterated in § 411.15(m)(2). Similarly, § 411.15(p)(2)(ii) specifically excludes payment for incident to services in skilled nursing facilities (SNFs). Consequently, we defined non-institutional settings as all settings except hospitals and SNFs, and we do not plan to define ASCs and CMHCs as institutional settings.

Comment: Many commenters wanted us to restrict the definition of auxiliary personnel so that only certain individuals may perform a given incident to service. For example, they want us to mandate that only audiologists may perform cochlear implant rehabilitation services as incident to services. Likewise, they want us to permit only physical or occupational therapists to perform physical or occupational therapy as incident to services. In support, they noted that section 4541(b) of the BBA amended section 1862(a)(20) of the Act and required that physical or occupational therapy furnished as an incident to service meet the same requirements outlined in the physical or occupational therapy benefit set forth in sections 1861(g) and (p) of the Act.

Response: We have not further clarified who may serve as auxiliary personnel for a particular incident to service because the scope of practice of the auxiliary personnel and the supervising physician (or other practitioner) is determined by State law. We deliberately used the term any individual so that the physician (or other practitioner), under his or her discretion and license, may use the service of anyone ranging from another physician to a medical assistant. In addition, it is impossible to exhaustively list all incident to services and those specific auxiliary personnel who may perform each service.

Comment: Many commenters wanted us to re-emphasize that incident to services set forth in section 1861(s)(2)(A) of the Act do not include Medicare benefits separately and independently listed in the Act, such as diagnostic services set forth in section 1861(s)(3). Some even requested that we not permit these separately and independently listed services to be rendered as incident to services.

Response: We realize, as did the Congress with the enactment of section 4541(b) of the BBA, that many services—even those that are separately and independently listed—can be furnished as incident to services. However, this fact of medical practice is not inconsistent with our policy. We maintain that a separately and independently listed service can be furnished as an incident to service but is not required to be furnished as an incident to service. Furthermore, even if a separately and independently listed service is provided as an incident to service, the specific requirements of that separately and independently listed service must be met. For instance, a diagnostic test under section 1861(s)(3) may be furnished as an incident to service. Nevertheless, it must also meet the requirements of the diagnostic test benefit set forth in § 410.32. Namely, the test must be ordered by the treating practitioner, and it must be supervised by a physician. Thus, if a test requires a higher level of physician supervision than direct supervision, then that higher level of supervision must exist even if the test is furnished as an incident to service. Accordingly, we decline to prohibit a separately and independently listed service from being rendered as an incident to service. Instead, we reiterate that a separately and independently listed service need not meet the requirements of an incident to service.

Comment: Recognizing that this proposal affords flexibility in the way physicians (or other practitioners) are hired by an office or clinic, one commenter requested that non-physician practitioners be permitted to stand as *locum tenens* (taking the place of) for other non-physician practitioners as well.

Response: This proposed rule does not alter in any way the current *locum tenens* policy.

Result of Evaluation of Comments

We are finalizing our proposed revisions to § 410.26 with the corrections noted above.

D. Anesthesia Services

We generally use the 1988 American Society of Anesthesiologists' (ASA) Relative Value Guide as the basis for the uniform relative value guide. This guide is used in all carrier localities to determine payment for anesthesia services furnished by physicians under Medicare Part B. We proposed using the ASA base unit values from the 1999 guide beginning in CY 2002 for eight codes with ASA base unit values that were different from CMS's values (specifically, CPT codes 00810; 00902; 01150; 01214; 01432; 01440; 01770; and 01921). These are older codes and, while we accepted the ASA base unit value initially, the ASA has changed this base unit subsequently and no additional adjustment was made by us to the base unit. For CPT codes 00142 and 00147, we proposed maintaining the current base unit values although they differed from the ASA values because values for these two codes were established under the ''inherent reasonableness'' process in 1987.

Comment: The ASA identified additional CPT codes 00548, 00700, 00800, and 01916 with different base unit values in the most current ASA guide from our base unit values.

Response: We are accepting the ASA's comments subject to the following clarification. In all, 12 codes were presented where the ASA base unit differs from our base unit. Of these, code 01921, which appeared on the list in the August 2, 2001 proposed rule, will be deleted in 2002. Since this code has been deleted and will no longer be used, we will not assign base units to it and, as a result, only 11 codes will be considered.

These additional four codes were added to CPT before CY 2000. New and revised codes starting in CY 2000 and for subsequent years are evaluated on a code-specific basis under our usual process after we receive recommendations from the RUC. Thus, because we review the RUC recommendations and may make changes based on them, there could be differences between the ASA guide and our base unit values beginning in 2000. If the RUC or other commenters recommend and we agree to a base unit different from what ASA recommends, we will use that value and not the ASA

value, even though it may be published in the ASA's guide.

Result of Evaluation of Comments

The complete list of 11 CPT codes for which we will assign the ASA base unit values instead of the current CMS base unit values are as follows:

Code	CMS	ASA
00548	15	17
00700	3	4
00800	3	4
00810	6	5
00902	4	5
01150	8	10
01214	10	8
01432	5	6
01440	5	8
01770	8	6
01916	5	6

A related issue is the treatment of base unit values for new codes for 2002 as discussed in section V. The RUC reviewed the work values for 19 new anesthesia codes for 2002. We agree with the RUC on 17 of these codes but recommend lower values for 2 codes. The RUC recommended 9 units for CPT code 00797 (anesthesia for gastric restrictive procedure for morbid obesity) and we proposed 8 units. The RUC recommended 3 units for CPT code 01968 (cesarean delivery following neuraxial labor analgesia/anesthesia—list separately in addition to the code for primary procedure), and we proposed 2 units. (See section V for additional information on the valuing of these new anesthesia services.)

Result of Evaluation of Comments

We are implementing the base units for the 11 existing codes where there are differences between the ASA's guide and our base units and for which we received comments. In addition, we are implementing the base units which the RUC recommended for 17 new codes and the base units which we recommended and which are lower than the RUC's recommendation for 2 new codes.

E. Performance Measurement and Emerging Technology Codes

In the August 2, 2001 proposed rule (66 FR 40383) we included a discussion of the two new categories of CPT codes: Performance Measure codes, referred to as Category II CPT codes, which are intended to facilitate data collection; and, Emerging Technology codes, referred to as Category III CPT codes, which are intended to track new and emerging technologies.

For the Performance Measure codes, which have a syntax of four digits followed by the letter ''F,'' we stated that no values would be placed on the Performance Measure codes and no additional payment would be made for the use of these codes. Practitioners would, however, be able to report them on their Medicare bills to enable us to track these services.

For the Emerging Technology Codes, which have a syntax of four digits followed by the letter ''T,'' we stated that we would pay, on a case-by-case basis in specific situations, when we determine that the codes represent services that are not, in fact, experimental, but have been shown to be safe and effective. If the coverage policy is not consistent with the existing tracking codes, a Medicare-specific code may need to be developed to allow payment for the service. Thus, only specific emerging technology codes would be recognized for Medicare payment.

Comment: Commenters expressed appreciation for our recognition of these new categories of CPT codes. However, one commenter believed that we should refrain from categorically denying payment for category III (emerging technology) CPT codes, because these CPT codes may sometimes warrant payment. Another commenter believed that we were proposing not to pay for these codes at all. The commenter recommended that we clarify in the final rule that carriers may determine if payment should be made for a particular emerging technology code.

Response: We believe that these codes will serve a useful purpose. We regret that some commenters believed that the discussion in the proposed rule implied that these services should not be covered. We only intended to indicate that by publishing these codes we are not indicating that we would pay for these services in all instances. As the commenter indicates, coverage of emerging technologies and payment for these services is at the discretion of the carriers. We also want to clarify that our carriers will be able to incorporate these codes only after they are entered into our system during our regularly scheduled updates and not as soon as the AMA posts them on the CPT web site.

Result of Evaluation of Comments

We would like to clarify the intent of our proposal regarding emerging technology CPT codes. The emerging technology CPT codes will be published in the physician fee schedule with a status indicator of ''C'' to indicate that coverage and payment of these services is at the discretion of the carrier. The only exceptions will be for those emerging technology CPT codes that describe services for which Medicare has issued an NCD. In these situations, coverage will be based on the NCD, and we may establish national payment or may leave payment to the discretion of the carriers. It is also possible that an NCD or an established payment policy may foreclose coverage and/or payment for an emerging technology CPT code. In summary, we will finalize our proposal to allow both the CPT Performance Measure Codes (that is, codes with four digits followed by the letter ''F'') and Emerging Technology Codes (that is, codes with four digits followed by the letter ''T'') to be listed on Medicare bills and provide payment for the emerging technology codes as determined by the carrier.

F. Payment Policy for CPT Modifier 62 (Co-Surgery)

The CPT modifier code 62 is used to report the work of co-surgeons. Currently, if we pay for co-surgery, we pay a total of 125 percent of the fee schedule amount to the co-surgeons who each receive half of this total payment. In the August 2, 2001 proposed rule (66 FR 40383), we stated that we would be examining our payment policies for co-surgery to consider possible ways to ensure that they reflect current clinical practices and properly reflect the relative resources and work effort required to perform these services. We outlined several issues under consideration and specifically solicited information to assist us in deciding whether to make a future proposal affecting payments for co-surgery.

Result of Evaluation of Comments

Commenters responded to the specific questions in the proposed rule. Many commenters believe that the current payment policy is reasonable and that the focus should be on education efforts to ensure the appropriate use of the modifier. We will review carefully the information the commenters have provided. If we determine that we need to proceed with a change in payment policy for co-surgery, the change would be proposed as part of future rulemaking.

III. Implementation of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Public Law 106–554), enacted on December 21, 2000, provides for revisions to policies applicable to the physician fee

schedule. These revisions are presented below.

A. Screening Mammography

Medicare has paid for screening mammography since January 1, 1991. Section 1834(c) of the Act governing these screenings did not include screening mammography under the physician fee schedule; it provided for payment under a separate statutory methodology. Section 104 of BIPA amends section 1848(j)(3) of the Act to include screening mammography as a physician's service for which payment is made under the physician fee schedule beginning January 1, 2002. In the August 2001 proposed rule, we proposed amending §§ 405.534 and 405.535 to reflect the inclusion of screening mammography as a physician's service which will be payable under the physician fee schedule. In addition, we proposed amending § 414.2 to include screening mammography under the definition for physicians' services. In accordance with part 414, payments for screening mammography will be resource-based and will have geographic adjustments that reflect cost differences among areas as do all other services under the physician fee schedule, including diagnostic mammography.

The following is a summary of the RVUs proposed for the professional and technical components (PC and TC) of a screening mammography, CPT code 76092, under the physician fee schedule.

Professional Component

A screening mammography service typically requires the same number of views as a unilateral diagnostic mammography. Therefore, for screening mammography, we proposed a physician work RVU of 0.70 based on the physician work established for a unilateral diagnostic mammography. This value is equal to the proposed work RVUs from the 5-year review of physician work for CPT code 76090, unilateral diagnostic mammogram (see June 8, 2001 proposed notice, ''Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule''). Since we believe that the practice expense and malpractice expense for the professional component of screening mammography is similar to the professional component of unilateral diagnostic mammography, we proposed establishing 0.25 practice expense RVUs and 0.03 malpractice RVUs for the PC of screening mammography.

Technical Component

We proposed valuing the technical component of screening mammography using a methodology that updates the original statutory limit for the technical component of screening mammography of $37.40, by the cumulative increase in physician fee schedule rates between 1992 and 2001 (see the August 2, 2001 proposed rule (66 FR 40384) for specific information on methodology). This resulted in proposed practice expense and malpractice RVUs for the technical component of screening mammography of 1.27 and 0.06, respectively.

Overall, the total proposed RVUs associated with the combined PC and TC of CPT code 76092 were 2.31 (0.70 work RVUs, 1.52 practice expense RVUs, and 0.09 malpractice expense RVUs).

New Technology Mammography

The BIPA also required us to determine whether the assignment of new HCPCS codes is appropriate for both screening and diagnostic mammography performed using new digital technologies.

We determined that new HCPCS codes are appropriate for the new digital technology mammography beginning January 1, 2002. We proposed three separate codes for directly taking a digital image (one for screening and one each for unilateral and bilateral diagnostic). We also proposed a single add-on code for computer-aided diagnosis with conversion of standard film images to digital images, since, at the time of the development of the proposed rule, the FDA approved computer-aided diagnosis only for screening mammography. Following is a summary of our proposed coding and payment methodologies for digital mammography.

Screening Mammography, Direct Digital Image (Gxxx1)

We proposed HCPCS code Gxxx1 to report screening mammography performed using direct digital images as opposed to mammography that is performed using the standard film images associated with CPT code 76092, or conversion of a standard film image to a digital image. For the PC of HCPCS code Gxxx1, we proposed 0.70 work RVUs, 0.28 practice expense RVUs, and 0.03 malpractice expense RVUs. For the TC of HCPCS code Gxxx1, for which there is no physician work associated, we proposed 2.50 practice expense RVUs and 0.06 malpractice RVUs.

Diagnostic Mammography, Unilateral, Direct Digital Image (Gxxx2)

We proposed HCPCS code Gxxx2 to report unilateral diagnostic mammography performed using direct digital images as opposed to mammography performed using the standard film images associated with CPT code 76090, or conversion of a standard film image to a digital image.

For the professional component of HCPCS code Gxxx2, we proposed 0.70 work RVUs, 0.28 practice expense RVUs, and 0.03 malpractice expense RVUs. For the TC of HCPCS code Gxxx2, with which there is no physician work associated, we proposed 1.99 practice expense RVUs and 0.05 malpractice expense RVUs.

Diagnostic Mammography, Bilateral, Direct Digital Image (Gxxx3)

We proposed HCPCS code Gxxx3 to report bilateral diagnostic mammography that is performed using direct digital images as opposed to mammography performed using the standard film images associated with CPT code 76091, or conversion of a standard film image to a digital image.

For the PC of HCPCS code Gxxx3, we proposed 0.87 work RVUs, 0.34 practice expense RVUs, and 0.03 malpractice expense RVUs. For the TC of HCPCS code Gxxx3, with which there is no physician work associated, we proposed 2.47 practice expense RVUs and 0.06 malpractice expense RVUs.

Computer-Aided Detection, With Either Direct Digital Image or Conversion of Standard Film Images to Digital Images (HCPCS Code Gxxx4)

We proposed HCPCS code Gxxx4 to report conversion of standard film images to digital images when used in conjunction with computer-aided diagnosis software. This code was proposed as an add-on code that can be billed only in conjunction with the primary service, CPT code 76092, based on our understanding that the only FDA-approved use of the computer-aided diagnosis mammography software is with screening film images. If there are other FDA-approved uses of computer-aided diagnosis, we stated we would allow for use of Gxxx4 as an add-on to other mammography services.

For the PC of code Gxxx4, we proposed 0.06 work RVUs, 0.02 practice expense RVUs, and 0.01 malpractice expense RVUs. For the TC of HCPCS code Gxxx4, with which there is no physician work associated, we proposed 0.41 practice expense RVUs and 0.01 malpractice expense RVUs.

Since publication of the proposed rule, the FDA has also approved the use

of computer-aided diagnosis with diagnostic mammography.

Comment: The majority of comments received from manufacturers, specialty organizations, individuals, and representatives of the Congress were supportive of our proposed payment of mammography services beginning January 1, 2002. The general consensus from commenters was that the proposed 21 and 26 percent increase, respectively, in payments for unilateral and bilateral diagnostic mammography, as a result of the 5-year review of work (see section IV), the new resource-based payment for screening mammography, the new resource-based payments for both digital screening and digital diagnostic mammography, and the payments for computer-aided diagnosis reflect the relative resources associated with each individual service.

However, two commenters still believe that the 21 percent and 26 percent increase in payments for unilateral and bilateral diagnostic mammography, respectively, was still inadequate to cover the costs of these services.

Response: In agreement with the majority of comments received, we continue to believe that our proposed relative values are an accurate reflection of the resources associated with the provision of these services.

Comment: We received comments that suggested that Medicare payment is inadequate to cover the cost of screening mammography. One commenter stated that, due to the Federally-mandated Mammography Quality Standards Act (MQSA) requirements intrinsic to mammography (both screening and diagnostic), it is difficult to use the current methodology to account for all practice expenses. This commenter did indicate support for our proposal to develop practice expense RVUs for screening mammography using a comparison to unilateral diagnostic mammography.

Response: We are currently using the ''no work'' methodology to price the technical component of diagnostic mammography and a special method for the technical component of screening mammography. We believe that most costs associated with mammography services are likely to be associated with the technical component. At this time, we plan to continue using these methods to establish the practice expense relative value units for the technical component of mammography services. However, if we propose a change to the methodology for no-work services in the future, we agree that it is important to consider whether MQSA costs are incorporated in the data sources we are using to develop RVUs.

Comment: We received two comments that suggested Medicare should not pay for screening mammography using the physician fee schedule until payment is set at an appropriate level so as not to require reduction in payments for other services. The commenters were concerned about the reduction in payment for other services that would result from the increase in payment for screening mammography using the methodology we proposed. These commenters acknowledged that the statute requires us to pay for screening mammography using the physician fee schedule. One commenter appreciated the significant effort that CMS put forth to comply with the mandate.

Response: As indicated by the comments, section 104(a) of the BIPA requires us to pay for screening mammography using the Medicare physician fee schedule beginning January 1, 2002. We estimate that payment in 2002 for screening mammography under the statutory methodology would have been about $71, which is less than the $81 that Medicare will pay under the physician fee schedule. Since screening mammography is paid under the physician fee schedule, the increase in payment will be subject to the budget neutrality calculations under section 1848(c) of the Act. The increase in payment, although large, will have little effect on payment for other physician fee schedule services. The required adjustment to other physician fee schedule payments is less than −0.1 percent.

Comment: We received comments about coding for new technology screening mammograms. These comments indicated support for our proposed coding but noted that two developments have since occurred that we could not have taken into account in our proposed rule. First, CPT created a new code for computer-aided detection (CAD) as an add-on for screening mammography. Second, the Food and Drug Administration approved use of CAD for diagnostic mammography. The commenters requested that we use the CPT code for CAD as an add-on to screening mammography and create a slightly modified HCPCS alphanumeric code as an add-on for diagnostic mammography. The modification would specify that the alphanumeric code is to be used as an add-on for diagnostic mammography. Commenters also suggested that we accommodate potential future FDA approved uses of CAD as an add-on to digital mammography through necessary coding and payment changes as soon as possible without having to await the next rulemaking cycle.

Response: We agree with the comments about coding of CAD. Medicare will recognize CPT code 76085 for CAD as an add-on to screening mammography and procedure code G0236 as an add-on to diagnostic mammography. The code descriptors make clear that the CPT code is for use as an add-on to screening mammography and the alphanumeric code is an add-on to diagnostic mammography. Payment for the revised codes follows the proposed rule approach for physician work, practice expense and malpractice for all mammography services. There may be slight changes to the RVUs for practice expenses as a result of updated information included in this final rule that affect all physician fee schedule services.

In response to the comment about potential future FDA approved uses of CAD as add-on to digital mammography, it is possible that additional coding changes will be necessary or that editorial revisions to existing codes will allow for CAD to be paid as an add-on for digital mammography. We would like to coordinate our efforts with those of the CPT to minimize the need for alphanumeric codes and additional CPT codes.

Comment: One commenter expressed concern about the payment associated with the Outpatient Prospective Payment System for all forms of mammography.

Response: Any issues related to the Outpatient Prospective Payment System are outside the scope of this regulation and will be addressed by a separate regulation.

Comment: One commenter asked for clarification on Federally Qualified Health Centers (FQHC) reimbursement for screening mammography and other new services.

Response: Any issues related to FQHC reimbursement are outside the scope of this regulation.

Comment: One commenter expressed concern that CMS did not work more closely with the CPT codes in the establishment of coding for digital mammography.

Response: Whenever possible, CMS works with the American Medical Association's CPT Editorial Panel to establish coding for new technologies. The AMA CPT Editorial Panel has not established codes for digital mammography; therefore, CMS proactively established temporary G-codes for the digital mammography and

computer-aided detection for diagnostic mammograms.

Comment: One commenter indicated that the malpractice expense for screening mammography should be higher than the unilateral diagnostic value of 0.03 since most mammography malpractice claims arise from allegations of cancers not detected or inappropriate follow-up of screening mammograms, not diagnostic studies. In addition, the screening mammography malpractice apportionment should be reversed for the PC and TC portions as the malpractice expense and risk is primarily with the interpreter of the screening mammogram, not the facility producing the technical component.

Response: We will consider the malpractice RVUs for these services interim for 2002 and will examine this issue with respect to the methodology used to establish malpractice RVUs.

Result of Evaluation of Comments

We will finalize our proposed relative values, because we believe they are an accurate reflection of the cost associated with the provision of these services. Additionally, we will also establish a temporary G-code (G0236) for the recent FDA approval of computer-aided detection used in conjunction with diagnostic mammography.

TABLE 3.—2002 MAMMOGRAPHY PAYMENTS

CPT [1] HCPCS	MOD	Descriptor	Work RVU	Practice Expense RVU	Malpractice RVU	Total
76090		Mammogram, one breast	0.70	1.25	0.08	2.03
76090	26	Mammogram, one breast	0.70	0.25	0.03	0.98
76090	TC	Mammogram, one breast	0.00	1.00	0.05	1.05
76091		Mammogram, both breast	0.87	1.54	0.09	2.50
76091	26	Mammogram, both breast	0.87	0.30	0.03	1.20
76091	TC	Mammogram, both breast	0.00	1.24	0.06	1.30
76092		Mammogram, screening	0.70	1.44	0.09	2.23
76092	26	Mammogram, screening	0.70	0.25	0.03	0.98
76092	TC	Mammogram, screening	0.00	1.19	0.06	1.25
G0202		Mammogram, screen, dir dig	0.70	2.52	0.09	3.31
G0202	26	Mammogram, screen, dir dig	0.70	0.30	0.03	1.03
G0202	TC	Mammogram, screen, dir dig	0.00	2.42	0.06	2.48
G0204		Diag mammo, bilat, dir dig	0.87	2.73	0.09	3.69
G0204	26	Diag mammo, bilat, dir dig	0.87	0.35	0.03	1.25
G0204	TC	Diag mammo, bilat, dir dig	0.00	2.38	0.06	2.44
G0206		Diag mammo, unilat, dir dig	0.70	2.20	0.08	2.98
G0206	26	Diag mammo, unilat, dir dig	0.70	0.28	0.03	1.01
G0206	TC	Diag mammo, unilat, dir dig	0.00	1.92	0.05	1.97
G0236		Computer aided detect, diag	0.06	0.31	0.02	0.39
G0236	26	Computer aided detect, diag	0.06	0.02	0.01	0.09
G0236	TC	Computer aided detect, diag	0.00	0.29	0.01	0.30
76085		Computer aided detection	0.06	0.31	0.02	0.39
76085	26	Computer aided detection	0.06	0.02	0.01	0.09
76085	TC	Computer aided detection	0.00	0.29	0.01	0.30

[1] CPT codes and descriptions only are copyright 2002 American Medical Association. All Rights Reserved. Applicable FARS/DFARS Apply.

B. Screening Pelvic Examinations

Section 101 of the BIPA amends section 1861(nn)(2) of the Act (effective July 1, 2001) to provide that a woman who does not qualify for annual coverage of a screening pelvic examination under one of the statutory exceptions, qualifies for coverage of a screening pelvic examination (including a clinical breast examination) once every 2 years rather than once every 3 years.

In the August 2, 2001 proposed rule, we made conforming changes to § 410.56 (Screening Pelvic Examinations) of the regulations to reflect this statutory provision that has been implemented through sections 4603, 3628.1 and 4731 of the Medicare Carrier Manual, the Medicare Intermediary Manual, and the Medicare Hospital Manual, respectively.We received only one specific comment on the new screening pelvic examination proposal. That comment supported our proposed rule and recognized that the regulations are consistent with the Medicare law.

Result of Evaluation of Comments

We are adopting our proposal to conform the regulations to the law to provide coverage for biennial screening pelvic examination for women not at high risk for cervical or vaginal cancer, effective July 1, 2001.

C. Screening for Glaucoma

Section 102 of the BIPA provides for Medicare coverage under Part B for screening for glaucoma for individuals with diabetes, a family history of glaucoma, or others determined to be at ''high risk'' for glaucoma effective for services furnished on or after January 1, 2002. The statute provides for coverage of glaucoma screening, including (1) a dilated eye examination with an intraocular pressure measurement, and (2) a direct ophthalmoscopy or a slit-lamp biomicroscopic examination, subject to certain frequency and other limitations.

In the August 2, 2001 rule, we proposed a new § 410.23 (Screening for Glaucoma: Conditions for and Limitations on Coverage), to provide for coverage of the various types of glaucoma screening examinations specified in the statute. As provided in the statute, this new coverage allows payment for one glaucoma screening examination every year. To implement the statutory provisions, we proposed definitions for the following terms—screening for glaucoma, eligible beneficiaries, and direct supervision.

In keeping with the language of section 102(b) of the BIPA we proposed defining the term ''screening for glaucoma'' to mean a dilated eye examination with an intraocular pressure measurement and a direct ophthalmoscopy or a slit-lamp biomicroscopic examination for the

early detection of glaucoma. This section also provides that the screening examinations that are to be covered under Medicare are to be furnished by or under the direct supervision of an optometrist or ophthalmologist who is legally authorized to furnish these services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished. These are services that would otherwise be covered if furnished by a physician or as incident to a physician's professional service. We also proposed incorporating this language in § 410.23.

We used the term ''eligible beneficiaries'' to indicate who may qualify for the new screening glaucoma benefit, and we proposed defining that term to include—individuals with diabetes mellitus, individuals with a family history of glaucoma, and African-Americans age 50 and over. As explained in the August 2 proposed rule, based on our review of the medical literature, and consultation with staff of the National Eye Institute and representatives of the American Academy of Ophthalmology and the American Optometric Association, we interpreted the statutory language, ''individuals determined to be at high risk for glaucoma'' to include Medicare beneficiaries who are African-Americans age 50 and over.

We felt that the medical evidence available at this time was only sufficient to support inclusion of African-Americans age 50 and over in the statutory ''high risk'' category, in addition to individuals with diabetes and those with a family history of glaucoma who are covered separately under the new screening benefit. However, we specifically solicited public comment on the appropriateness of including other individuals in the statutory definition of ''high risk'' for glaucoma, with supporting documentation from medical literature.

Section 102(b) of the BIPA provides that the glaucoma screening examination is to be furnished by or under the direct supervision of an ophthalmologist or optometrist who is legally authorized to furnish such services under State law or regulation in which the services are furnished. We proposed defining the term ''direct supervision'' as that term is defined in § 410.32(b)(3)(ii) for purposes of the oversight of covered diagnostic laboratory services as they are performed in the office setting. Specifically, for purposes of screening glaucoma we proposed defining the term ''direct supervision'' to mean that the ophthalmologist or optometrist must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. The definition states that the term ''direct supervision'' does not mean the physician must be present in the room when the procedure is performed.

We also proposed conforming changes to specify an exception to the list of examples of routine physical checkups excluded from coverage in §§ 411.15(a)(1) and 411.15(k)(9) for glaucoma screening examinations that meet the frequency limitation and the conditions for coverage that we are specifying under new § 410.23.

We received six comments that generally supported the proposal to implement section 102 of BIPA that provides for Medicare coverage of screening for glaucoma. Four of these comments were submitted by national medical associations, one was submitted by a pharmaceutical company, and another was provided by a consulting group. Only one commenter had a suggestion for revising the specific coverage provisions of the proposal.

Comment: One commenter responded to our invitation to the public in the proposed rule to submit comments on the question of whether it might be appropriate to include other individuals (and not just African-Americans over age 50) in the statutory definition of those at ''high risk'' for glaucoma. First, the commenter cites an article from the medical literature that notes that ''one of the clearest factors relating to increased glaucoma prevalence is age.'' (Gilchrist. Ophthalmic Physiol Opt 2000) Second, the commenter refers to other eye experts in the research of the epidemiology of glaucoma who have suggested that ''the appropriate age at which screening might be most effective is 6 to 10 years younger among those of African descent because of the earlier onset of disease.'' (Quigley and Vitale. Invest Ophthalmol Vis Sci 1997) Third, the commenter states that the latter conclusion is supported by data showing that in African-Americans who eventually develop glaucoma, the disease is present in 25 percent by age 54, 50 percent by age 65, and 75 percent by age 75. The commenter cites from the same Quigley article that comparable ages for these percentages of disease development in non-African-Americans are 64, 72, and 81 years, respectively. Finally, the commenter concludes that this literature supports a policy that would provide the glaucoma screening benefit for non-African Americans at an age 6 to 10 years older than for African-Americans (for example, 50 years of age), or beginning at age 56 to 60 years of age.

Response: We believe that the commenter has not interpreted the results of the Quigley and Vitale studies correctly. The article by Quigley and Vitale reported the results of a meta-analysis and statistical modeling to estimate the prevalence and incidence of glaucoma. In general, results from meta-analysis and remodeling are often limited by the quality and comparability of the original source data. In the proposed rule, we used data reported directly from the Baltimore Eye Study (Tielsch, et al. JAMA 1991) and the Beaver Dam Eye Study (Klein, et al. JAMA 1992), two of the largest published studies on glaucoma. These studies indicated that the prevalence of glaucoma in non-African-Americans starts to increase after the age of 65 to 70 years, whereas the prevalence increases much earlier in African-Americans. Our decision to include African-Americans in the statutory category of those at ''high risk'' for glaucoma was based on these studies and the increased prevalence of glaucoma in African-Americans.

Although we have decided not to add new populations to the definition of high risk at this time, the comment does raise the issue of how we should revise the definition in the future, if there is evidence to do so. We have decided to revise the proposed language in § 410.23(a)(2) so that it specifically refers to ''individuals in the following high risk categories'' to make it more consistent with the statute. This new structure for the regulation language will permit CMS to more easily add high risk groups to the glaucoma screening benefit through the rulemaking process should the evidence in the medical literature warrant it.

Payment for Glaucoma Screening

We believe that services provided as part of glaucoma screening will often overlap with services a physician provides during a patient encounter for ophthalmological services without requiring any additional work or practice expense. Therefore, we proposed bundling payment for glaucoma screening when it is provided on the same day as an evaluation and management (E/M) service or when it is provided as part of any ophthalmology service. In instances when glaucoma screening is the only service provided or when it is provided as part of an otherwise non-covered service (for example, CPT code 99397, preventive services visit,) we proposed the following HCPCS codes and payments:

Gxxx5, Glaucoma Screening Furnished by a Physician for High Risk Patients.

For physician work and for malpractice, we proposed work and malpractice RVUs of 0.45 and 0.02, respectively, by crosswalking these values from CPT code 99212. Gxxx6, Glaucoma Screening Furnished Under the Direct Supervision of a Physician for High Risk Patients.

For physician work and for malpractice, we believe this new HCPCS code represents a level of work comparable to other E/M services performed ''incident to'' a physician's service and therefore proposed to crosswalk the work and malpractice RVUs from CPT code 99211 (E/M service that may not require the presence of a physician) which are 0.17 and 0.01, respectively.

For non-facility settings, we proposed the following practice expense inputs for both of the above HCPCS Codes—clinical staff time-certified ophthalmic medical technologist/certified ophthalmic technician/registered nurse: five minutes; equipment: screening lane; and supplies: ophthalmology visit supply package.

Comment: We received a comment from the American Academy of Ophthalmology (AAO) agreeing with our decision to bundle glaucoma screening with other E/M services and with our decision to create two levels of glaucoma screening services based on whether or not the physician performed the evaluation. The AAO also agreed with our proposal regarding RVUs for glaucoma screening performed ''incident to'' but commented that the level of payment for glaucoma screening performed by a physician was too low. They believe that payment rate should be a blend between CPT codes 99202 (Office or other outpatient visit for evaluation and management of a new patient) and 99213 (Office or other outpatient visit for evaluation and management of an established patient). This is based on the expectation that some patients receiving the service will be ''new'' patients to the ophthalmologist while others will have previously seen the ophthalmologist and therefore be ''established'' patients.

The AAO proposes that for 2002, payment be equivalent to CPT code 99202 for both physician work and practice expense, that for 2003, payment be equivalent to a 4.4 percent/95.6 percent blend of CPT codes 99202 and 99213 for both physician work and practice expense, that for 2004, payment be equivalent to a blend of 4.5 percent/95.5 percent blend of CPT codes 99202/99213, and that for 2005 and thereafter, payment be equivalent to a blend of 4.6 percent/95.4 percent of CPT codes 99202/99213. The AAO believes that the amount of history, physical examination, and medical decision making required for glaucoma screening approximates the amount of history, physical examination and medical decision making required for CPT code 99202 at the time of the first glaucoma screening and approximates the amount of history, physical examination, and medical decision making required for 99213 at the time of subsequent glaucoma screenings.

The American Optometric Association (AOA) echoed the AAO's comments concerning the crosswalk for physician work. They also noted that the practice expense inputs should be crosswalked to the intermediate ophthalmologic codes.

Response: We are finalizing our proposal to assign 0.45 work RVUs and .02 malpractice RVUs to Gxxx5, glaucoma screening performed by a physician (now G0117). This service is a screening service and therefore cannot be easily compared to the key components of a level III evaluation and management service (CPT code 99213). We also believe that the vast majority of beneficiaries receiving this service will be patients who have been previously seen by the ophthalmologist performing the service and, therefore, CPT code 99202 would not be an appropriate crosswalk for this service. We believe the work required for this service is similar whether or not the patient is ''new'' or ''established''. Patients undergoing a screening service have no chief complaint or history of present illness. To perform this service, the only historical information required is a determination as to whether the beneficiary meets the criteria in the law, (for example, is at high risk for glaucoma). Therefore, the requirements for taking a history are actually less than the requirements of CPT code 99212. Additionally, the physical examination requirements are specified in the statute and are similar to the requirements of CPT code 99212. Furthermore, the vast majority of patients undergoing screening will not have glaucoma, so the typical screening service will require routine medical decision making. For those few patients with glaucoma who will need to schedule a return visit, the medical decision making is straightforward. Therefore, the glaucoma screening requirements are similar to CPT code 99212. Our decision to assign 0.45 work RVUs to this service is also consistent with the time required to perform the service and places it in correct rank order with regard to other screening services payable under Medicare. We have decided to accept the recommendation of AOA on practice expense inputs and will crosswalk the inputs from CPT code 92012, brief ophthalmic exam performed on an established patient, rather than using the practice expense inputs from CPT codes 99202 and 99213 as suggested by AAO.

Because we received no comments on the RVUs for the Gxxx6 code, Glaucoma Screening Furnished Under the Direct Supervision of a Physician for High Risk Patients (now G0118), we will implement this as proposed and will assign .17 work RVUs and .01 malpractice RVUs. For practice expense, we will also crosswalk this code to CPT 92012.

Comment: Several commenters noted that medical technicians do not have the education or training to provide screening glaucoma services. One commenter noted that ophthalmic medical personnel (OMP) are not licensed by State regulatory agencies and are precluded from ordering medications, including eyedrops. The commenter states that, according to the Joint Commission on Allied Health Personnel in Ophthalmology and the Association of Technical Personnel in Ophthalmology, OMPs cannot be independent practitioners, cannot diagnose or treat eye disorders and cannot prescribe medications. Since a dilated eye exam requires medication, the OMP cannot perform the exam without the patient first being seen by an ophthalmologist or optometrist.

Response: The regulation is drafted based on the statutory provision; however, it does not supersede any State laws or licensing requirements.

Result of Evaluation of Comments

We are adopting our proposal to include only African-Americans age 50 and over in the statutory category of those at ''high risk'' for glaucoma. We are revising the regulation in § 410.23(a)(2) to read ''Eligible beneficiary means individuals in the following high risk categories.'' This should allow CMS to more easily add high risk groups by rulemaking should the medical evidence warrant it.

For G0117 Glaucoma Screening for High Risk Patients Furnished by an Optometrist or Ophthalmologist—we will assign 0.45 work RVUs, .02 malpractice RVUs and we will crosswalk practice expense inputs from CPT code 92012.

For G0118 Glaucoma Screening for High Risk Patients Furnished Under the Direct Supervision of an Optometrist or Ophthalmologist—we will assign .17 work RVUs and .01 malpractice RVUs.

For practice expense we will also crosswalk this code to CPT code 92012.

D. Screening Colonoscopy

Before the enactment of the BIPA, sections 1861(pp)(1)(C) and 1834(d)(3)(E) of the Act authorized Medicare coverage of screening colonoscopies once every 2 years for individuals at high risk for colorectal cancer. Individuals not at high risk for colorectal cancer did not qualify for coverage of screening colonoscopies under the colorectal cancer screening benefit, but they did qualify for coverage of other colorectal cancer screening examinations specified in the statute. These other examinations that were covered for individuals not at high risk for colorectal cancer included screening fecal-occult blood tests, screening flexible sigmoidoscopies, and screening barium enema examinations at certain frequency intervals specified in the statute and the regulations at § 410.37 (Colorectal cancer screening tests).

Section 103 of the BIPA amended sections 1861(pp)(1)(C), 1834(d)(2)(E)(ii), and 1834(d)(3)(F) of the Act to add coverage of screening colonoscopies once every 10 years for individuals not at high risk for colorectal cancer. However, in the case of an individual who is not at high risk for colorectal cancer, but who has had a screening flexible sigmoidoscopy within the last 4 years, the statute provides that payment may be made for a screening colonoscopy only after at least 47 months have passed following the month in which the last screening flexible sigmoidoscopy was performed. In addition, the statute provides that, in the case of an individual who is not at high risk for colorectal cancer but who does have a screening colonoscopy performed on or after July 1, 2001, payment may be made for a screening flexible sigmoidoscopy only after at least 119 months have passed following the month in which the last screening colonoscopy was performed.

In view of the statutory changes, we are conforming §§ 410.37(e) and 410.37(g) (related to limitations on coverage of screening colonoscopies and screening flexible sigmoidoscopies) to make them consistent with the new provisions of the statute that have been implemented through manual provisions of the Medicare Carriers Manual, the Medicare Intermediary Manual Part III, and the Medicare Hospital Manual in transmittal numbers 6097, 1824, and 7069, respectively, in February 2001.

Payment for Screening Colonoscopy

Payment for screening colonoscopy will be made under HCPCS code G0121: colorectal screening; colonoscopy for an individual not meeting criteria for high risk. As with current code G0105, screening colonoscopy for an individual at high risk, payment will be made at the level for a diagnostic colonoscopy, CPT code 45378, because the work is the same whether a procedure is screening or diagnostic. As the statute requires that, for both individuals who are or are not at high risk, if, during the course of the screening colonoscopy, a lesion or growth is detected that results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as colonoscopy with biopsy or removal should be billed and paid rather than HCPCS code G0105 or G0121.

We received four comments in support of the proposal to conform the regulations to the Medicare law implementing the new screening colonoscopy provision (section 103 of the BIPA) for individuals not at high risk for colorectal cancer. One of the commenters, however, did have a suggestion for how we could improve the manual instructions that we issue to our carriers on this subject.

Comment: The commenter suggests that we instruct our Medicare carriers to identify which International Classification of Diseases—Volume Nine (ICD–9) codes are acceptable to use in conjunction with the interim GO121 code that has been proposed for billing for covered screening colonoscopies performed for individuals not at high risk for colorectal cancer. The commenter stated that our failure to do this for screening flexible sigmoidoscopy code G0104 in the billing instructions we issued to our carriers in 1998 created problems for everyone concerned because individual carriers adopted a variety of acceptable ICD–9 codes, but did not inform the public under what circumstances the examinations were covered and when they were not.

Response: We are not aware of the problems stated above with respect to the Medicare billing codes for screening flexible sigmoidoscopies in 1998. In addition, we have not received any complaints about the new billing instructions that we released to our carriers in February of this year in conjunction with the interim G0121 code that was issued (effective July 1, 2001) for use in billing for screening colonoscopies for individuals not at high risk for colorectal cancer. Since individuals who might qualify for coverage under this new screening benefit are those who would not be at ''high risk'' for colorectal cancer, it is not clear to us why the physician billing for the service would need to provide any ICD–9 code for the examination to the carrier for Medicare payment to be made. We do not require that such information be submitted to the carrier at the present time in these circumstances.

Result of Evaluation of Comments

We are implementing our proposal as stated above. In view of the comment, we will review the matter, and we will take any necessary action that might be deemed appropriate.

E. Medical Nutrition Therapy

Section 105 of the BIPA amended section 1861(s)(2) of the Act to authorize Medicare Part B coverage of medical nutrition therapy (MNT) for certain beneficiaries who have diabetes or a renal disease, effective for services furnished on or after January 1, 2002. This new benefit is similar to a benefit initially established by section 4105 of the BBA as a component of the diabetes outpatient self-management training (DSMT) benefit. The DSMT benefit, described at section 1861(qq) of the Act, is a comprehensive diabetes training program, of which nutrition training is only one component.

Consistent with section 105(a)(3) of the BIPA, we considered the protocols of the American Dietetic Association (ADA) and the National Kidney Foundation (NKF) regarding medical nutrition therapy training for both diabetes and renal disease in order to establish criteria for coverage of these services. Because the protocols were inconclusive with respect to duration and frequency issues, we proposed to determine the duration and frequency of the benefit through the NCD process rather than through the rulemaking process.

We proposed to set forth the provisions regarding medical nutrition therapy at Part 410, subpart G and at § 414.64. The MNT provisions of the final rule follow.

Definitions (§ 410.130)

We defined ''renal disease'' for the purpose of this benefit as only chronic renal insufficiency and post-transplant care provided after discharge from the hospital. We proposed to limit post-transplant care to care furnished within 6 months after discharge from the hospital, if the transplant is viable and effective, because, under such conditions, we believe the beneficiary would no longer have renal disease and

would not be eligible to receive the benefit under the statutory provision. We specifically solicited comments on this proposed time period, and requested that the commenters support their comments with articles from medical journals. We also established definitions of ''diabetes'', ''renal disease'', and ''chronic renal insufficiency'' for the purpose of this benefit using definitions from the Institute of Medicine report, ''The Role of Nutrition in Maintaining Health in the Nation's Elderly,'' published in 2000.

We proposed defining ''episode of care'' as a time period not to exceed 12 months, starting with the assessment (based on a referral from a physician), and including all covered interventions. Finally, in accordance with the statute, we defined MNT services as nutritional diagnostic, therapy, and counseling services provided by a registered dietitian or nutrition professional for the purpose of managing disease.

Medical Nutrition Therapy (§ 410.132)

At § 410.132(a), we proposed the conditions for coverage of MNT services. Specifically, we proposed that Medicare Part B pay for MNT services furnished by a registered dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by the beneficiary's treating physician. We proposed to limit the definition of physician to ''treating physician'' to ensure that the physician establishing the need for MNT is actually treating the beneficiary for a covered chronic disease and that the therapy is coordinated with the care being provided by the treating physician.

We proposed that the services covered consist of nutritional assessment, interventions, reassessment, and follow-up interventions. We chose not to define the specific components of the benefit in more detail because we anticipated that registered dietitians and nutritionists would use nationally recognized protocols, such as those developed by the ADA, as they normally would in their practice. As previously mentioned, we also proposed to use the NCD process to develop duration and frequency limits.

At § 410.132(b), we set forth the coverage limitations for MNT services. In accordance with section 1861(s)(2)(V)(ii) of the Act, we provided that MNT services would not be covered for beneficiaries on dialysis for end-stage renal disease. We did not exclude all beneficiaries who are diagnosed with end-stage renal disease because a few individuals with end-stage renal disease do not receive maintenance dialysis, and the statute specifically excludes beneficiaries receiving maintenance dialysis under section 1881 of the Act. The other provisions of this section outlined the coordination of referrals for MNT for diabetes and renal disease, and coordination of MNT and DSMT services.

Eligibility for MNT services will be dependent upon diagnoses and referrals made by the treating physician. At § 410.132(c), we proposed that referral only be made by the treating physician when the beneficiary has been diagnosed with diabetes or a renal disease, with documentation maintained by the referring physician in the beneficiary's medical record. Referrals must be made for each episode of care.

At § 410.132(d), we discussed requirements regarding reassessment and follow-up interventions. Specifically, we proposed that reassessments and follow-up interventions would only be covered when the referring physician determined that there was a change of diagnosis or medical condition within an episode of care that made a change in diet necessary.

Provider Qualifications (§ 410.134)

The BIPA specifies how we must define ''registered dietitian or nutrition professional'' for the purposes of this benefit, and allows for the grandfathering of nutrition professionals licensed or certified by States at the time of its enactment. The proposed qualifications for a registered dietitian or nutrition professional are set forth at § 410.134, and include alternative criteria for recognition of registered dietitians in States that do not provide for licensure or certification of these individuals.

We received nearly 1,000 comments on the MNT portion of the proposed rule. The most frequently received comments concerned: the definitions of diabetes, renal disease, and treating physician; the coordination of the diabetes self-management training and MNT benefits; and proposed reimbursement. We also received comments about provider qualifications.

Comment: We received a large number of comments that stated we had defined diabetes and renal disease too narrowly and asked for further clarification of the definitions.

Response: Our definition of diabetes does not specifically state how physicians should perform lab tests to determine if a beneficiary should be diagnosed with diabetes. However, as with the national protocols for medical nutrition therapy, we assume that physicians will conduct tests in accordance with nationally accepted clinical guidelines, which require testing on multiple occasions to determine a diagnosis of diabetes. We are clarifying our definition of diabetes by adding a sentence to further explain the etiology of the disease. We also have extended coverage to include gestational diabetes for the few Medicare beneficiaries who would need such coverage. We believe that we do not have the statutory authority to extend coverage to beneficiaries who have not yet been diagnosed with diabetes.

We also expand the definition of renal disease in this final rule. First, we clarify that beneficiaries with end-stage renal disease who are not receiving dialysis are eligible for the service. In addition, we have expanded the time period in which we will cover MNT for beneficiaries who have received a renal transplant to 36 months, to bring the coverage into conformance with the Medicare eligibility period for individuals under age 65.

Comment: A few commenters requested that we change our definition for renal disease to encompass all patients with glomerular filtration rates (GFR) below 60. The GFR is the measurement of renal function and has a range in normal adult males of 98 to 150 ml/min/1.7m^2 and in normal adult females of 106 to 132 ml/min/1.7^2. The commenters believe that we did not fulfill the intent of the Congress.

Response: We disagree with the comment. Neither the BIPA nor its legislative history indicates any specific intention regarding how to define renal disease for purposes of eligibility for this benefit. Section 4108 of the BBA required the Department of Health and Human Services to contract with the National Academy of Sciences (NAS) to examine the benefits and costs associated with extending Medicare coverage for certain services, including medical nutrition therapy. We believe the NAS Institute of Medicine (IOM) report, ''The Role of Nutrition in Maintaining Health in the Nation's Elderly,'' published in 2000, provides a reasonable definition for determining the scope of the benefit. In that report, ''renal disease'' is defined as chronic renal insufficiency, end-stage renal disease, and the beneficiary's condition following renal transplant. The GFR rate for chronic renal insufficiency (GFR of 13 to 50 ml/min/1.73m^2) used in the proposed rule was also in the IOM report.

The IOM report did not cover the period of time MNT should be available to beneficiaries following a renal

transplant. The Congress has authorized us to provide a reasonable interpretation of how much coverage will be provided for beneficiaries after renal transplant.

The suggested eligibility criterion of a GFR under 60 suggested by commentators appears to be too expansive, because typically the GFR for beneficiaries after they receive a transplant never goes above 60. We also received comments recommending that we match our coverage to the length of time an under-65 beneficiary is entitled to post-transplant coverage. We agree that this is a reasonable criterion for our coverage of MNT services for post-renal-transplant beneficiaries.

Comment: We received a large number of comments expressing concern about our use of the term ''treating physician''. Most commenters believe that the term does not include both primary care physicians and specialists. One commenter believes we exceeded our statutory authority. Also, some commenters believe that we should allow any physician to provide a referral for the service.

Response: We did not intend to exclude primary care physicians from the term ''treating physician''. In this final rule, we now define the term ''treating physician'' to mean the primary care physician or specialist coordinating care for the beneficiary with diabetes or renal disease.

Regarding our statutory authority, the statute, as amended at section 1861(s)(2)(V)(iii) of the Act, clearly states that the Secretary has authority to impose other criteria, after considering protocols established by dietetic or nutrition professional organizations. Requiring referral by the treating physician is within this statutory authority. We continue to believe that we must assure the quality of services received by Medicare beneficiaries. Therefore, our coverage guidelines must require coordination of care for beneficiaries with chronic diseases in order to assure that quality. We have not changed the final rule to allow any physician to make the referral for MNT.

Comment: We also received comments concerning the definition of the benefit and episode of care.

Response: As stated in the proposed rule, we relied on the national dietetic therapy protocols of major organizations to define the basic benefit. In seeking to understand the reason for these comments, we discovered that the use of the term ''reassessment and follow-up interventions'' in §§ 410.132(a) and (d) was confusing to many commenters. In the national protocols, reassessments and follow-up interventions are always considered part of the basic service. In the proposed rule, we had used the terms to define a special circumstance that happens only when a beneficiary has a change in medical condition or diagnosis.

In this final rule, we clarify our policy by eliminating the use of the terms ''reassessment'' and ''follow-up interventions''. We also have changed the language slightly in several other parts of the final rule to help clarify our intent, such as adding, ''treatment regimen'' as another reason why we would allow additional coverage in special circumstances. Our definition of ''episode of care'' (except in the case of coordination of services with initial DSMT and gestational diabetes) is based on our intent to pay providers of the service more efficiently by conforming the definition to our claims processing requirements. Our intent continues to be that dietitians and nutritionists should follow national MNT protocols.

Comment: Some commenters stated that the DSMT and MNT benefits for beneficiaries with diabetes should only be coordinated to the extent of reducing the total of number of MNT hours by one hour.

Response: In the proposed rule, we assumed that all of the MNT benefit for diabetes would be provided as part of the initial DSMT benefit and that follow-up DSMT and MNT for diabetes should be fully coordinated. In our discussions with interested organizations concerning the amount of services that should be covered for the NCD process, great concern was expressed about the coordination of the DSMT and MNT benefits. Therefore, we have spent a great deal of time researching this issue. We have found no evidence to date to suggest that the language of the proposed rule should be changed for this requirement. However, because we are still developing our NCD concerning the duration and frequency of the MNT benefit, we will continue to consider any evidence that might lead to the conclusion that additional hours should be covered when both benefits are provided during the same time period.

Until such time as an NCD alters this requirement, if initial DSMT and MNT benefits for diabetes are provided in the same 12 month episode of care, only 10 total hours of services will be covered, regardless of whether the hours are covered as MNT, DSMT, or a combination of both. In situations where follow-up DSMT and MNT for diabetes is provided, only the total amount of hours allowed under the MNT benefit will be covered. (The MNT cap will be applied to any DSMT services provided to a beneficiary during the follow-up period, until such time as an NCD alters this requirement.)

Comment: We received comments that MNT for a diagnosis of renal disease and MNT for a diagnosis of diabetes should not be fully coordinated.

Response: In this final rule, we are not changing this requirement because the provision at § 410.132(d) (in this final rule § 410.132(b)(5)) already provides for additional coverage in this situation and we believe that additional coverage is not necessary. However, we are clarifying that beneficiaries receiving initial DSMT can receive the full initial DSMT benefit.

Comment: One commenter was concerned that providers that had completed a full course of study of dietetics or nutrition after completion of a bachelor's degree would be excluded. We also received comments asking us to clarify the requirements further.

Response: We agree that individuals that complete the full course of study of an accredited dietetics or nutrition program after completion of a bachelor's degree would still meet the intent of the legislation. Therefore, we have altered the regulatory language to include these individuals. However, we will require our contractors to require the practitioner to provide proof of completion of the course of study in addition to proof of receiving the degree.

In situations where the individual is credentialed as a registered dietitian by an organization appropriate for this purpose, we will recognize that credential as proof that the individual meets both the education and experience required in the regulation. We have added language at §§ 410.134(a) and (d) to change the final rule.

Comment: A commenter noted that State licensure requirements vary considerably; providers will need to obtain multiple licenses when they perform services in more than one State; and providers will have to meet different requirements if State licensure provisions change.

Response: The statutory intent to recognize State licensure and State licensure requirements is clear. We cannot require States to have similar licensure requirements, recognize licensure by other States, or to provide for grandfathering of providers when State licensure laws change. Therefore, we have not changed the final rule to reflect these comments.

Payment for Medical Nutrition Therapy (§ 414.64)

Section 105(c) of the BIPA requires that we pay for medical nutrition therapy services at 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the physician fee schedule for the same services if the services had been furnished by a physician. Based upon consultation with the American Dietetic Association (ADA) to assess the types of resource inputs used to furnish a 15-minute medical nutrition therapy session by a registered dietitian or professional nutritionist, we proposed the following:

For CPT code 97802—Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes, we did not propose physician work RVUs for this service, based on the statutory provision that specifically provides that medical nutrition therapy services may only be furnished by registered dietitians or nutrition professionals. For practice expense, we proposed 0.47 RVUs and, for malpractice, we proposed 0.01 RVUs for a total of 0.48 RVUs.

For CPT code 97803—Reassessments and intervention, individual, face-to-face with the patient, each 15 minutes, we proposed 0.0 work RVUs, 0.34 practice expense RVUs and 0.01 malpractice RVUs for a total of 0.35 RVUs.

For CPT code 97804—Group, 2 or more individuals, each 30 minutes, we proposed 0.0 work RVUs, 0.14 practice expense RVUs and 0.01 malpractice RVUs for a total of 0.15 RVUs. To determine payment, the RVUs shown above would need to be multiplied by the physician fee schedule conversion factor and 0.85 (to reflect the statutory requirement that payment be 85 percent of the amount determined under the physician fee schedule).

We also stated that, consistent with the definition in the CPT's Physical Medicine Rehabilitation codes, a group is considered to be 2 or more individuals and that Medicare co-payments and deductibles would apply for medical nutritional therapy services.

Comment: The American Dietetic Association (ADA) and many individuals submitted comments concerning the proposed reimbursement rate for medical nutrition therapy services. They stated that the proposed reimbursement rate for these services is too low and would result in limited beneficiary access to these services since private practice dietitians will choose not to participate. Some commenters referenced reimbursement rates currently paid by private insurers of $85 to $125 for 1 to 1½ hours for an initial visit and $85 per hour for follow-up. They believe that the proposed rate for Medicare is far short of what was envisioned by the Congress. Commenters indicated that the statute clearly states that medical nutrition therapy payment should be 80 percent of the lesser of the actual charge or 85 percent of the amount determined under the physician fee schedule for the same service, provided by a physician. According to commenters, physicians who are also registered dietitians, use E/M codes 99213 through 99215 and 99244 when providing medical nutrition therapy services. The commenters stated that E/M codes 99203 through 99205 are appropriate reference points for determining medical nutrition therapy payment. The commenters also stated that any refinement of medical nutrition therapy values should be based on the underlying E/M codes that they believe are the statutory basis for medical nutrition therapy payment. While commenters acknowledge that physicians may perform other tasks besides nutritional assessment, therapy and counseling during an office visit, they believe those additional services are the basis for the Congress' instruction to reimburse non-physician providers of medical nutrition therapy at 85 percent of the amount physicians receive. The AMA's Health Care Professionals Advisory Committee (HCPAC) submitted a comment that suggested there should be physician work for medical nutrition therapy. This group provides recommendations on valuing services for codes used by non-physician providers. The HCPAC indicated that it evaluated each of the medical nutrition therapy codes and compared them to services that are available to other providers but not nutritionists (for example, physical therapy services). The comment further stated that the 15 percent reduction should not apply because the HCPAC took this into account when developing the recommendations. The HCPAC further added that there should be work values for medical nutrition therapy just as there are for physical and occupational therapy.

Response: We have reviewed the statute and legislative history. There is no indication that Congress envisioned a particular payment amount or expected us to use an E/M service to determine the value of medical nutrition therapy. Section 105(c) of the BIPA states that ''the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) of the Act for the same services if furnished by a physician.'' The BIPA Conference Report indicates that payment will equal ''the lesser of the actual charge for the service or 85 percent of the amount that would be paid under the physician fee schedule if such services were provided by a physician.'' The statute and Conference Report direct us to establish the physician fee schedule amount for nutrition therapy services. The Medicare allowed charge would equal 100 percent of the physician fee schedule amount if the services are performed by a physician and 85 percent of the physician fee schedule amount if the services are performed by a registered dietitian or nutrition professional. The commenters suggest that physicians currently bill for an E/M service when they provide nutrition services. We do not believe that it is appropriate to compare medical nutrition therapy provided by a registered dietitian to an E/M service provided by a physician. Registered dietitians do not take medical histories, they are not trained to and do not perform physical examinations, nor do they make medical decisions. Furthermore, when physicians use an E/M code to report the provision of counseling or coordination of care, they typically have also performed a medical history, physical examination, and engaged in medical decision making as part of that service. If such an individual performed a service that met the requirements of an E/M service, then it would be be appropriate for him or her to report an E/M service. Further, we note that the E/M services include not only an amount attributable to physician work, but also payment for physician practice expenses. For instance, a level 3 new patient office visit (CPT code 99203) includes payment for 50 minutes of nurse time. A level 3 established patient office visit (CPT code 99213) includes 36 minutes of nurse time. Both of these codes include additional compensation for medical equipment and supplies that are typically used in an office visit but are not used as part of a medical nutrition therapy service. If we were to adopt the commenters' view and crosswalk values for medical nutrition therapy to an E/M service, we would be including payment not only for the counseling service of the practitioner, but also, inappropriately for the costs of clinical personnel that are not involved in the nutrition therapy service.

Commenters indicated that the statute established the 85 percent adjustment to account for activities that are typically performed by a physician during an E/M service are not performed by a nutritionist. The statute and legislative history do not indicate that the 85 percent adjustment is intended to serve this purpose. In fact, the commenters themselves note that ''consistent with other non-physician providers, reimbursement is set at a percentage of the physician's fee schedule.'' Under the physician fee schedule, we will pay a physician 80 percent of 100 percent of the physician fee schedule amount, and, if a non-physician practitioner provides an identical service, Medicare pays 80 percent of 85 percent of the physician fee schedule amount. For instance, under CPT code 99213, a level 3 established patient office visit is one of the most common services provided by physicians, physician assistants and nurse practitioners. Even though the service is considered to be identical, we can by law pay a physician assistant and nurse practitioner only 85 percent of what we pay a physician to do the same service. Thus, in the case of other practitioners, the percentage does not reflect that a non-physician practitioner provides fewer services than a physician. Because there is no indication in the statute that the 85 percent adjustment should apply differently in the context of medical nutrition therapy than for other services performed by non-physician practitioners, we believe it is appropriate to pay 80 percent of 100 percent of the physician fee schedule amount when medical nutrition therapy is provided by a physician and 80 percent of 85 percent of the physician fee schedule amount when the service is provided by a registered dietitian or nutrition professional.

In response to the comment about payment rates of private insurers for medical nutrition therapy, we cannot use such information in a relative value system to establish payment. Section 1848(c) of the Act requires us to establish RVUs that recognize the relative resources involved in furnishing different physician fee schedule services. Thus, our role is to establish the appropriate relative payment amounts. The total payment amount is determined under a formula prescribed in section 1848(d) of the Act. We have no authority to change the formula.

In response to the HCPAC recommendation, we reiterate that it is inappropriate to compare medical nutrition therapy services to E/M services performed by physicians. While medical nutrition therapy may be performed by a physician who is also a registered dietitian, this does not make it a physician's service that requires a work RVU. Physicians may occasionally perform other services that have no physician work, such as chemotherapy administration or the technical component of a diagnostic x-ray test. When such services with no physician work are performed by a physician, we do not establish a physician work RVU just because the service was performed by a physician in that instance. Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy services. In these circumstances, we will pay the physician 80 percent of 100 percent of the physician fee schedule amount. In this unusual circumstance, we are paying for a medical nutrition therapy service provided by a physician under section 1861(s)(2)(V) and not a physician's service under section 1861(s)(1) of the Act.

Comment: One comment indicated that the 85 percent adjustment should not apply because the RVUs we used are not based on physician work or physician practice expenses to deliver the service. This commenter indicated that we proposed an inadequate payment by not following the statutory scheme and proceeded to apply a 15 percent discount that is neither fair nor reasonable.

Response: The statute requires us to establish a physician fee schedule amount for the service and pay 80 percent of 100 percent of the amount if the service is provided by a physician and 80 percent of 85 percent if the service is provided by a registered dietitian or nutrition professional. We initially anticipated that physicians would never bill Medicare for medical nutrition therapy services because they generally would not meet the statutory requirements to be considered registered dietitians or nutrition professionals. In this circumstance, we agree that it seems unusual to apply a reduction for a service that seldom would be furnished by a physician. However, we believe that the statute requires that Medicare payment be based on the 85 percent level. We understand that, although not common, there are physicians who do meet the statutory requirements to be considered registered dietitians or nutrition professionals. In these circumstances, our payment to the physician will be based on 100 percent of the physician fee schedule amount, not the 85 percent that we will pay to a registered dietitian or nutrition professional. We believe the statute would not allow a physician who does not meet the statutory requirements for a registered dietitian or nutrition professional to be paid for a medical nutrition therapy service. If a physician provides medical nutrition counseling as part of a patient encounter that meets the requirements for an E/M service, the physician can bill Medicare for a physician's service.

Comment: We received one comment requesting that we clarify that Medicare will pay qualified providers in private practice settings or physician offices where they may be independent contractors. The commenter also asked how we intend to pay for medical nutrition therapy in the hospital outpatient department. The commenter also asked for clarification on reassignment of payment if a registered dietitian is an employee of physicians or hospital outpatient facilities.

Response: Medicare will pay qualified dietitians and nutrition professionals who enroll in the Medicare program regardless of whether they provide medical nutrition therapy services in an independent practice setting, hospital outpatient department or any other setting, with the exception of services provided to patients in an inpatient stay in a hospital or skilled nursing facility. In these circumstances, our payment to the hospital or skilled nursing facility includes payment for medical nutrition therapy. If a qualified practitioner provides medical nutrition therapy in any other setting, including a private practice setting, section 1833(a)(1)(T) of the Act requires that Medicare payment equal 80 percent of the lesser of actual charges or 80 percent of 85 percent of the amount determined under the physician fee schedule. Payment in the hospital outpatient department will be made under the physician fee schedule, not under the hospital outpatient prospective payment system.

Current rules regarding reassignment of benefits would apply to medical nutrition therapy. We want to emphasize that medical nutrition therapy cannot be provided incident to a physician's service unless the physician also meets the qualifications to bill Medicare as a registered dietitian or nutrition professional.

Comment: Commenters objected to the methodology used to establish the proposed RVUs for this service. They believe it is inappropriate to use the top-down or no-work pool methodology to determine medical nutrition therapy payment. They believe that medical nutrition therapy payment should not be based on comparison to a preventive medicine code (CPT code 99401) in the zero-work pool methodology. The

commenters indicated that preventive medicine services omit the problem-oriented components of the comprehensive history, as well as other essential assessment points, such as the patient's chief complaint and history of present illness. They disagree with our assertion in the proposed rule that physicians do not perform nutrition services and assert that it is inappropriate to use the top-down or zero-work methodology to establish the RVU for medical nutrition therapy.

Response: We use the top-down methodology or no-work pool methodology to price the practice expense RVUs for all services priced under the Medicare physician fee schedule. Given that the statute indicates that medical nutrition therapy should be paid using the physician fee schedule, we believe it is reasonable and appropriate to use the same methodologies that we use to develop RVUs for other physician fee schedule services. With respect to use of the preventive medicine service, we used a service that we felt had similar practice expenses to medical nutrition therapy. It is not clear why practice expenses for a counseling service would differ based on the health status of the patient.

Comment: A commenter representing dietitians asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97803 was set at 72.9 percent of proposed RVUs for CPT code 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe that the value of CPT codes 97802 and 97803 should be identical. The commenters indicated that E/M services provided by physicians do not receive the same discount. The commenter also stated that the payment for CPT code 97804 was less than for other group services and gave the example of a nurse or pharmacist providing nutrition instruction under the diabetes self-management training benefit.

Response: We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15 minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services. (We note that the RVU units between the proposed and final rule show some marginal change because of changes made in the practice expense methodology that affect all physician fee schedule services). We do not agree with the comment that ''evaluation and management services provided by physicians do not receive the same discount.'' E/M service are not time based services and, as stated above, for many reasons are inappropriate comparisons to medical nutrition therapy service codes.

Comment: Many commenters stated that co-payments must be structured so that they are not barriers to the medical nutrition therapy benefit.

Response: Section 105(c) of the BIPA modifies section 1833(a)(1) of the Act to add subparagraph (T) that requires that Medicare payment equal 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under physician fee schedule. The statute requires the same coinsurance for medical nutrition therapy services that applies to other Part B services.

Comment: Commenters suggested that initial medical nutrition therapy sessions for treatment of diabetes or renal disease should be billed under CPT code 97802 and subsequent medical nutrition therapy sessions should be billed under CPT code 97803. New diagnoses due to a change in medical condition or unanticipated complications should be billed under CPT code 97802 and subsequent medical nutrition therapy sessions should be billed under CPT code 97803.

Response: At the present time, we are requiring that medical nutrition therapy be reported by using CPT codes 97802, 97803, and 97804. We will revisit our coding requirements when we publish the NCD for medical nutrition therapy. The NCD will set forth the structure of the medical nutrition therapy benefit in detail. We will make a decision concerning creation or modification of codes and creation of modifiers for reporting medical nutrition therapy once the NCD has been published. Until the NCD is published, creation or modification of codes and creation of modifiers would be premature. Therefore, we are requiring that the initial individual medical nutrition therapy visit be reported as CPT code 97802 and all follow up visits (for interventions and reassessments) for individual medical nutrition therapy be reported as CPT code 97803. All group medical nutrition therapy visits should be reported as CPT code 97804 whether they are initial or follow up visits.

Comment: Commenters urged us to define medical nutrition therapy descriptors consistently. They stated that the descriptors in Table 5 of the proposed rule should agree with the descriptors in § 414.132.

Response: We agree. We will make the descriptors for medical nutrition therapy consistent with the nomenclature in CPT and our regulations.

Comment: We received a comment that recommended that we consider including additional items in the practice expense inputs for medical nutrition therapy. The commenter indicated that inputs should include staff costs for training on billing procedures, Health Insurance Portability and Accountability Act training, audit expenses, and other costs resulting from Medicare policies and procedures. The commenter indicated that expenses of registered dietitians in private practice differ little from other practitioners.

Response: There are two major data sources used in the practice expense methodology—estimates of direct inputs and aggregate practice expense per hour information from the AMA's Socioeconomic Monitoring Survey. At this time, we are using the practice expense per hour for all physicians to establish the practice expense RVUs for medical nutrition therapy. We are not currently using the estimates of direct expenses for medical nutrition therapy because the services are valued in the no-work pool. However, we are researching alternatives to the no-work pool that would allow all no-work services to be priced under the top-down methodology. If we develop such an alternative, the estimates of direct expenses will be important in determining the RVUs for medical nutrition therapy. Indirect expenses are based on physician work and direct inputs. We believe that many of the costs identified by this commenter are indirect costs that would likely be included in practice expenses reported through the SMS survey. Since the commenter has suggested that practice expenses for private practice registered dietitians differ little from other

practitioners, we believe the average practice expense per hour for all physicians is sufficient to use in the practice expense methodology.

Result of Evaluation of Comments

The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the rate for CPT code 97802. We are also changing the payment rate for CPT code 97804 using the assumption that the code will normally be billed for 4 to 6 patients with the average of 5. Using these revised values, the payment rate for group medical nutrition therapy will approximate the hourly rate paid for other medical nutrition therapy services.

F. Telehealth Services

Beginning October 1, 2001, the BIPA amended section 1834 of the Act to specify that we pay a physician (as defined in section 1861(r) of the Act) or a practitioner (described in section 1842(b)(18)(C) of the Act) for telehealth services that are furnished via a telecommunications system to an eligible telehealth individual.

The BIPA defined Medicare telehealth services as professional consultations, office or other outpatient visits, and office psychiatry services identified as of July 1, 2000, by CPT codes 99241 through 99275; 99201 through 99215, 90804 through 90809 and 90862 (and as we may subsequently modify) and any additional service we specify. The BIPA defines an eligible telehealth individual as an individual enrolled under Part B who receives a telehealth service furnished at an originating site.

Section 1834(m) of the Act, as added by the BIPA, limited an originating site to a physician's or practitioner's office, hospital, critical access hospital, rural health clinic, or Federally qualified health center. Additionally, the BIPA specified that the originating site must be located in one of the following geographic areas:

- In an area that is designated as a rural health professional shortage area (HPSA) under section 332(a)(1)(A) of the Public Health Service Act.
- In a county that is not included in a Metropolitan Statistical Area (MSA).

However, an entity participating in a Federal telemedicine demonstration project that has been approved by, or receives funding from us as of December 31, 2000 would not be required to be in a rural HPSA or non-MSA.

The BIPA also required that we pay a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth beneficiary an amount equal to the amount that the physician or practitioner would have been paid under Medicare had the service been furnished without the use of a telecommunications system.

This section also provided for a facility fee payment for the period beginning October 1, 2001 through December 31, 2002, to the originating site of $20. For each subsequent year, the facility fee for the preceding year is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The BIPA also amended section 1833(a)(1) of the Act to specify that the amount paid must be 80 percent of the lesser of the actual charge or the amounts specified in new section 1834(m)(2) of the Act.

In order for us to have this benefit expansion implemented timely, we have used a program memorandum. The program memorandum was effective October 1, 2001. This final rule will be effective January 1, 2002.

The rule published on August 2, 2001 proposed to establish policies for implementing the provisions of section 1834(m) of the Act, as added by the BIPA, that change Medicare payment for telehealth services.

We proposed to revise § 410.78 to specify that Medicare beneficiaries are eligible for telehealth services only if they receive services from an originating site located in either a rural HPSA as defined by section 332(a)(1)(A) of the Public Health Services Act or in a county outside of a MSA as defined by section 1886(d)(2)(D) of the Act.

1. Definitions

Section 1834(m)(4)(F) of the Act, which was added by the BIPA and became effective for services beginning October 1, 2001, defined telehealth services as professional consultations, office and other outpatient visits, individual psychotherapy, pharmacologic management, and any additional service we specify. Additionally, this provision identified covered services by HCPCS codes identified as of July 1, 2000. We proposed to revise § 410.78 to implement this coverage expansion to include the following services (and corresponding CPT codes):

- Consultations (codes 99241 through 99275).
- Office and other outpatient visits (codes 99201 through 99215).
- Individual psychotherapy (codes 90804 through 90809).
- Pharmacologic management (code 90862).

We solicited comments regarding the guidelines that we should use to make additions or deletions of services. We also solicited comments about specific services that may be appropriate to be covered under the Medicare telehealth benefit.

In this final rule, we are specifying at § 410.78 that, except for the use of store and forward technology in the demonstration programs conducted in Alaska or Hawaii, an interactive telecommunications system must be used and the medical examination of the patient must be at the control of the physician or practitioner at the distant site. We are defining interactive telecommunications system as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and physician or practitioner at the distant site. We are also specifying that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

A patient need not be present for a Federal telemedicine demonstration program conducted in Alaska or Hawaii. We are specifying that for Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system. Additionally, we are specifying that the physician or practitioner at the distant site must be affiliated with the demonstration program.

We are defining asynchronous, store and forward technologies, as the transmission of the patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patient's medical condition and adequate for rendering or confirming a diagnosis or treatment plan. Finally, we are defining the originating site as the location of an eligible telehealth individual at the time the service being furnished via a telecommunications system occurs.

2. Conditions of Payment

The BIPA changed the telepresenter requirements. In accordance with section 1834(m)(2)(C) of the Act, a

telepresenter is not required to be present. Therefore, we would not require a telepresenter as a condition of Medicare payment.

Section 1834(m)(1) of the Act requires that Medicare make payments for telehealth services furnished via a telecommunications system by a physician or a practitioner (described in section 1842(b)(18)(C) of the Act). Non-physician practitioners described in this section of the Act include nurse practitioners, physician assistants, clinical nurse specialists, certified nurse midwives, clinical psychologists, clinical social workers, and certified registered nurse anesthetists or anesthesiologists' assistants. Section 1834(m)(2) of the Act specifies that we pay the physician or practitioner at the distant site who furnishes a telehealth service an amount equal to the amount that the physician or practitioner would have been paid under Medicare had the service been furnished without the use of a telecommunications system.

Certified registered nurse anesthetists and anesthesiologists' assistants would not be permitted to bill for and receive payment for a telehealth service under this provision. Under the Medicare program, these practitioners do not receive payment for office visits, consultation, individual psychotherapy, or pharmacologic management when these services are furnished without the use of a telecommunications system. Section 1834(m)(2) of the Act specifies that we pay to the distant site physician or practitioner an amount equal to what would have been paid for the service without the use of a telecommunications system. Therefore, certified registered nurse anesthetists and anesthesiologists' assistants would not receive payment for telehealth services.

We proposed at § 410.78 that, as a condition of Part B payment for telehealth services, the physician or practitioner at the distant site must be licensed to provide the service under State law.

Section 1834(m)(2)(A) of the Act specifies that the payment amount for the professional service is equal to the amount that would have been paid without the use of a telecommunications system. Medicare payment for physicians' services is generally based, under section 1848 of the Act, on the resource-based physician fee schedule. Payment to other health care practitioners listed earlier, authorized under section 1833 of the Act, is based on a percentage of the physician fee schedule payment amount. Therefore, we will pay for office or other outpatient visits, consultation, individual psychotherapy, and pharmacologic management services furnished by physicians at 80 percent of the lower of the actual charge or the fee schedule amount for physicians' services. We will also pay for services furnished by other practitioners at 80 percent of the lower of the actual charge or that practitioner's respective percentage of the physician fee schedule.

Section 1834(m)(2) of the Act provides for a professional fee for the physician or practitioner at the distant site (equal to the applicable Part B fee schedule amount) and a $20 facility fee for the originating site. Telepresenters are not required, unless one is deemed medically necessary by the physician or practitioner at the distant site. The BIPA does not address the issue of payment for the telepresenter. The Office of the Inspector General has advised us that permitting the physician or practitioner at the distant site to pay the telepresenter creates a significant risk under the anti-kickback statute. Therefore, we establish in § 414.65 that payments made to the distant site physician or practitioner for professional fees, including deductible and coinsurance (for the professional service), are not to be shared with the referring practitioner or telepresenter.

However, the telepresenter could bill and receive payment for services that are not telehealth services that a telepresenter would otherwise be allowed to provide under the Medicare statute, including services furnished on the same day as the telehealth service.

The BBA prohibited any payment for line charges or facility fees associated with a professional consultation via a telecommunications system. Section 1834(m)(2)(B) of the Act, as added by the BIPA, provides for a facility fee payment to the originating site, specifying that the amount of payment is 80 percent of the lesser of the actual charge or a facility fee of $20.00. The BIPA further specifies that, beginning January 1, 2003, the originating facility fee be increased annually by the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. Additionally, we clarify that the Geographic Practice Cost Index (GPCI) would not apply to the facility fee for the originating site. This fee is statutorily set and is not subject to the geographic payment adjustments authorized under the physician's fee schedule. The beneficiary is responsible for any unmet deductible amount and Medicare coinsurance. We would revise § 414.65 to provide for payment of a facility fee to the originating site.

Section 1834(m)(3) of the Act specifies that sections 1842(b)(18)(A) and (B) apply to physicians and practitioners receiving payment for telehealth services and to originating sites receiving a facility fee, in the same manner as they apply to practitioners. This section requires that payment for such services may only be made on an assignment-related basis. We did not reflect this provision in the proposed rule. Because this requirement is specified in the BIPA and we have no discretion, we are implementing it in this final rule in new § 414.65(d).

Comment: One commenter believed that requiring an originating site to be located in a rural HPSA or non-MSA county would not permit medical practitioners located in urban and suburban areas to offer telehealth services.

Response: We clarify that, as a condition of payment under Medicare, the originating site must be located in a rural HPSA or non-MSA county. The physician or practitioner at the distant site, who provides the telehealth service, is not subject to these limitations. For example, a psychologist in Salt Lake City, Utah would be able to provide a mental health visit to a beneficiary at a physician's office located in a non-MSA county.

Comment: We received various comments on the definition of an originating site. Many commenters believe that the list of facilities eligible to be a telehealth originating site should be expanded beyond those specified in the statute. Specific suggestions were received to include the patient's residence, skilled nursing facilities, nursing homes, and community mental health centers as originating site facilities within this provision. Another commenter suggested that we recommend legislative changes to remove the requirement that an originating site facility be located in a HPSA or non-MSA county.

Moreover, one organization requested that all locations included within the Alaska Native Tribal Health Consortium, including but not limited to outpatient health facilities recognized by the Indian Health Service as tribal health facilities be included as an originating site. The commenter requested that these sites be defined as an originating site regardless of whether they are certified as a Medicare Federally qualified health center or not.

Response: Section 1834(m) of the Act defines an originating site facility to include only a physician's or practitioner's office, hospital, critical access hospital, rural health clinic or Federally qualified health center.

Further, the Act specifies that the originating site must be located in a rural HPSA or non-MSA county. We do not have the legislative authority to expand the definition of a telehealth originating site beyond this provision. However, we will be studying this issue as part of a report to the Congress as authorized by section 223(d) of the BIPA.

Comment: One specialty college requested confirmation that the patient's medical information provided via store and forward telehealth is furnished to the physician or practitioner at the distant site in order to recommend or confirm a diagnosis and or treatment plan and not to provide a formal interpretation of imaging exams.

Response: The commenter is correct. Payment for services via store and forward technology under this provision does not include formal interpretation of an imaging exam. Medicare currently allows coverage and payment for medical services delivered via a telecommunications system that do not require a face-to-face ''hands on'' encounter. Section 2020(A) of the Medicare Carriers Manual addresses this issue and lists radiology, electrocardiogram, and electroencephalogram interpretations as examples of such services.

Comment: In the proposed rule, we requested comments on the guidelines that we should use to make additions or deletions to covered Medicare telehealth services. We also requested suggestions and comments about specific services that may be appropriate for payment under the Medicare telehealth benefit. In response to our solicitation, we received one comment regarding the guidelines we should use to make changes to the scope of Medicare telehealth coverage. Ten commenters provided specific suggestions regarding additional services that may be appropriate for the Medicare telehealth benefit.

Several commenters indicated that a psychiatric diagnostic interview, CPT code 90801, would be appropriate for Medicare telehealth payment. One association stated that the elements of this service are directly comparable to a new patient office visit, which the law defines as a telehealth service. Given that the law permits us to add additional services as appropriate, this commenter suggested that we include a psychiatric diagnostic interview within the definition of a telehealth service. Another association suggested that interactive psychotherapy, CPT codes 90810, 90812 and 90814, should be covered Medicare telehealth services. Interactive psychotherapy uses play equipment, physical devices and other mechanisms of non-verbal communication in an office or outpatient facility.

Several commenters suggested that telerehabilitation interventions that provide education, mentoring and consultation be included within the scope of Medicare telehealth coverage. The commenters specifically note that speech therapy and physical and occupational therapy should be included as telehealth services.

One consortium requested that all services provided under the Federal telehealth project in Alaska be included as covered telehealth services within this provision. The commenter believes that virtually all evaluation & management and psychiatry services should be included as Medicare telehealth services. Additionally, the commenter notes that many respiratory, digestive, ophthalmology and otorhinolaryngology services are appropriate for telehealth coverage.

One organization suggested that we consider guidelines similar to those currently in place for non-telehealth services. For instance, the commenter stated the service should be reasonable and necessary, safe and effective, medically appropriate, and provided within the purview of accepted standards of medical practice. The commenter stresses that the type of technology used to deliver the service should be secondary to the reasonable and necessary criteria.

Response: We will use these comments and suggestions to assist us in establishing guidelines for a telehealth coverage process and the addition of specific telehealth services that may be appropriate for Medicare beneficiaries. However, we do not believe it would be appropriate to expand the scope of telehealth services beyond the services explicitly listed in the Act until we have a process in place for adding new telehealth services.

Comment: With regard to the definition of a ''telecommunications system'', one organization encouraged us to permit store and forward technologies in other circumstances beyond federal telemedicine demonstration projects conducted in Alaska or Hawaii. The commenter believes that emphasis should be given to whether a particular service is reasonable and necessary rather than specific technology requirements. Moreover, the commenter stated that the face-to-face requirement is outdated for telehealth as well as other areas of the Medicare fee schedule and suggested that current technology, such as electronic mail, permits physicians to care for their patients even when the patient is not present.

Response: Section 1834(m) of the Act defines a telehealth service as office and other outpatient visits (99201 through 99215), professional consultations (99241 through 99275), individual psychotherapy (90804 through 90809), and pharmacologic management (90862). Further, the law specifies that payment must be equal to what would have been paid without the use of a telecommunications system.

As a condition of payment under Medicare, these services require a face-to-face patient encounter. We believe that the patient's presence and use of an interactive audio and video telecommunications system permitting the distant site practitioner to interact with the patient provides a reasonable substitute for a face-to-face encounter. The law provides for the use of asynchronous, store and forward technologies for delivering telehealth services only for telemedicine demonstration projects conducted in Alaska or Hawaii. We do not have the authority to expand the use of store and forward technology in delivering telehealth services.

Comment: One organization in a remote region requested that a definition of a telepresenter be added to § 410.78. The commenter suggested we permit a certified community health aid to present a patient when the aide is the only medical professional available to act as a telepresenter.

Response: The physician or practitioner at the distant site has the authority to determine whether it is medically necessary to require a telepresenter and, if necessary, the appropriate medical professional needed to present the patient. We do not believe it is appropriate for us to specify the type of medical professionals that are necessary to act as a telepresenter.

Comment: We received conflicting comments concerning interstate telehealth services. One organization requested that we require the physician or practitioner at the distant site to be licensed in the State where the originating site is located. On the other hand, an association requested clarification that the physician or practitioner at the distant site only needs to be licensed in the State where he or she is located and does not need to be licensed in the State where the originating site is located. Another commenter requested that we clarify that the service is considered rendered where the distant site physician or practitioner is located.

Response: We defer to State law regarding licensure issues. When the

State law for the originating site permits an out-of-State practitioner to provide a telehealth service, without being licensed in the State in which the originating site is located, Medicare would make payment for the telehealth service. However, when State law precludes an out-of-State practitioner from delivering a telehealth service, Medicare would not pay for that service.

We clarify that for payment purposes, the site of service for the telehealth service is the location of the physician or practitioner at the distant site. Given that section 1834(m) of the Act specifies that payment to the physician or practitioner at the distant site must be equal to the amount that would have been paid without the use of telehealth, it is appropriate to use the Geographic Practice Cost Index (GPCI) relevant to the distant site. However, our determination of the distant site physician's or practitioner's location as the site of service for Medicare payment is not intended to make a comment regarding the scope of medical practice.

Comment: One consortium believes that the proposed rule would not permit the physician or practitioner at the distant site to bill for a telehealth service when State or Federal law exempts a physician or practitioner from being licensed in the State in which he or she is currently employed. The consortium is a Federal telemedicine demonstration project that would be permitted to use store and forward telecommunications technologies in delivering telehealth services. The commenter notes that the State of Alaska exempts physicians or practitioners who are part of the military or Public Health Service that provide health care services in Alaska from its licensure requirements. Further, the commenter stated that Federal law authorizes health care professionals who are members of the military providing services for the Department of Defense to practice in any State provided the professionals are licensed in a State, the District of Columbia or other specific locations. The commenter also noted that current Medicare manual instructions specify that when a physician in a Federal hospital provides services to the public generally as a community institution, he or she may be considered as meeting the statutory definition of a physician even though he or she may not have a license to practice in the State in which he or she is employed.

Response: The telehealth provision does not affect State or Federal legislation providing certain physicians or practitioners an exemption from State licensure. When Federal or State law exempts a physician or practitioner from State licensure, then the physician or practitioner at the distant site is permitted to provide a telehealth service regardless of whether he or she is licensed within the State where he or she is employed.

Comment: One organization requested that § 414.65(a)(2) be revised to specify for what services the physician or practitioner who presents the patient could bill. The commenter believes that when the physician at the distant site determines that it is medically necessary for another practitioner to assist in providing the telehealth service, the telepresenter should be compensated. The commenter suggested that a telepresenter be permitted to bill for a consultation or confirmatory consultation.

Response: On the day the telehealth service occurs, the telepresenter may bill and receive payment for services that are not telehealth services that he or she would otherwise be allowed to provide under Medicare. A telepresenter, for example, a nurse practitioner, could bill for and be paid for a medically necessary office, outpatient or inpatient visit preceding or subsequent to a telehealth service. Additionally, the telepresenter could be paid for other medically necessary services requested by the physician or practitioner at the distant site. However, the physician at the distant site may not share any portion of the telehealth payment with the telepresenter or referring practitioner. We do not agree that § 414.65(a)(2) should be changed to specify the services for which a telepresenter can and cannot bill. This section implements payment for telehealth services only, and the Act does not provide for a payment to the telepresenter for telehealth services.

Comment: Many organizations and individual commenters expressed overall support for the revision of Medicare payment for telehealth. Specifically, commenters mentioned removal of the fee sharing requirement, relaxed conditions of payment, and the addition of non-MSA counties to the geographic areas eligible for telehealth under Medicare. The commenters noted that these changes will have a positive effect on health care delivery and will help provide services to areas where specialty care is sparse.

Response: We agree that the proposed revisions to Medicare telehealth coverage and payment policies, as authorized by the BIPA, remove significant barriers for physicians and practitioners wishing to provide telehealth services.

Comment: One commenter indicated that the cost of collecting the coinsurance for the originating site facility fee could easily exceed the amount the facility would collect from the beneficiary. The commenter encouraged us to permit originating sites to waive the coinsurance in those situations where the telehealth facility charge is the only amount to be billed to the beneficiary.

Response: We do not have the authority to eliminate the coinsurance requirement outright for telehealth originating sites. However, Medicare permits the waiver of coinsurance for limited situations. Section 5220 of the Medicare Carriers Manual specifies that physicians and suppliers may waive billing for or collection of coinsurance or deductibles for indigent patients or when the physicians' or suppliers' cost of billing or collecting exceeds or is disproportionate to the amounts to be collected. Documentation must be sufficient to support that costs for billing the beneficiary exceed or are disproportionate to the amount collected from the beneficiary. In this instance, the amount collected refers to 20 percent of the originating site telehealth facility fee.

We clarify that when the patient owes additional coinsurance to the originating site for other Medicare services, billing for the telehealth facility fee coinsurance amount may be consolidated with the coinsurance amount owed for those services. We believe that this would resolve the commenter's concern that the cost for billing and or collecting the coinsurance for a single facility fee could exceed or be disproportionate to the amount collected from the beneficiary.

Comment: One association submitted a number of comments that have payment implications for the Federally qualified health center benefit.

Response: These issues involve specific aspects of the Federally qualified health center payment methodology and are beyond the scope of this provision. We will take these comments into consideration in formulating future instructions for payment implications on FQHCs.

Result of Evaluation of Comments

We are implementing this provision as stated above.

G. Indian Health Service

The Indian health care system provides primary health care to many American Indian and Alaska Native Medicare beneficiaries. This system consists of programs operated by a Federal agency, the Indian Health

Service (IHS), and Federally funded programs operated by Indian tribes, tribal organizations, and urban Indian organizations (as those terms are defined in section 4 of the Indian Health Care Improvement Act). These programs deliver a range of clinical and preventive health services to their beneficiaries through a network of facilities including hospitals and outpatient clinics. Programs operated in IHS-owned or leased facilities, by IHS or by tribes or tribal organizations, are considered ''Federal providers'' by Medicare. Sections 1814(c) and 1835(d) of the Act generally prohibit payment to Federal providers, subject to exceptions contained in section 1880 of the Act for these IHS facilities. Before enactment of the BIPA, the exception in section 1880 of the Act was applicable only to IHS owned or leased hospitals, provider-based clinics, and skilled nursing facilities (regardless of whether the entity is tribally operated). The exception did not permit Medicare to pay for services furnished by IHS owned or leased free-standing outpatient clinics or to pay any IHS owned or leased facilities for services by physicians and other practitioners paid under a fee schedule.

Effective July 1, 2001, section 432 of the BIPA extends the exception in section 1880 of the Act to permit Medicare payments to hospitals and outpatient clinics (provider-based or free-standing), operated by the IHS or by a tribe or tribal organization, for services furnished by physicians and specified non-physician practitioners in or at the direction of the hospital or outpatient clinic. Payments for these services are made to the hospital or outpatient clinic, not to the physician or other practitioner. These payments are subject to the same situations, terms, and conditions as would apply if the services were furnished in, or at the direction of, a hospital or outpatient clinic that is not operated by the IHS or by a tribe or tribal organization. The payments include incentive payments for physicians furnishing covered physicians' services in rural or urban health professional shortage areas (HPSAs) if the usual HPSA criteria are met. (For further information see section 1833 of the Act and § 414.42 of our regulations.) Payments will not be made under these provisions to the extent that Medicare is otherwise paying for the same services under other provisions (for example, as part of a bundled payment, or if a tribal outpatient clinic continues to bill as a Federally qualified health center (FQHC)).

We have added a new § 410.46 to our regulations to reflect this new statutory provision. Due to the statutory effective date of July 1, 2001, we implemented this BIPA provision through program memorandum instructions.

Result of Evaluation of Comments

We received no comments on the statutory requirement to pay Indian Health Service and tribal hospitals and clinics for the services of physicians and other practitioners under Medicare fee schedules.

H. Pathology Services

The November 2, 1999 final rule (64 FR 59380) provided that, for services furnished on or after January 1, 2001, carriers would no longer pay claims to independent laboratories under the physician fee schedule for the technical component (TC) of physician pathology services for hospital inpatients. Before that rule, independent laboratories could bill the carrier under the physician fee schedule for the TC of a physician pathology service furnished to a hospital inpatient. Also, under that rule, independent laboratories would still have been able to bill and receive payment for the TC of physician pathology services furnished to patients who are not hospital inpatients.

Section 542 of the BIPA requires the Medicare carrier to continue to pay for the TC of physician pathology services when an independent laboratory furnishes these services to an inpatient or outpatient of a covered hospital. The BIPA provisions apply to TC services furnished during the 2-year period beginning January 1, 2001 and continuing through December 31, 2002. We informed the carriers and the intermediaries of this provision through program memorandum AB–01–47, which was issued in March 2001. This program memorandum requested the carriers to notify independent laboratories of this provision in their next regularly scheduled bulletin and to place this bulletin on their Internet web site. In the absence of further legislation, the policy of the November 1999 final rule will take effect for the TC of physician pathology services furnished to hospital patients after December 31, 2002. We have revised § 415.130 to conform to the statutory change in section 542 of BIPA concerning the payment for the TC of physician pathology services.

Result of Evaluation of Comments

We have received no comments on this issue.

IV. Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule; Responses to Public Comments on the Five-Year Review of Work Relative Value Units

A. Scope of Five-Year Review

This final rule includes the culmination of the 5-year review of work RVUs required by statute. The work RVUs affected by this review will be effective for services furnished beginning January 1, 2002.

In our June 8, 2001 proposed notice (66 FR 31028), we explained the process used to conduct the 5-year review of work RVUs. During the comment period we received approximately 35 public comments on approximately 900 codes. After review by our medical staff, we forwarded all of the comments we received concerning potentially misvalued services to the AMA's Specialty Society Relative Value Update Committee (RUC).

The RUC submitted work RVU recommendations for all of the codes we forwarded with the exception of the anesthesia codes and conscious sedation codes. We analyzed all of the RUC recommendations and evaluated both the recommended work RVUs and the rationale for the recommendations. If we had concerns about the application of a particular methodology, but thought the recommended work RVUs were reasonable, we verified that the recommended work RVUs were appropriate by using alternative methodologies. (For additional information on the review process, please see the proposed notice published June 8, 2001.)

B. Review of Comments (Includes Table 4 Work RVU Refinements of 5-Year Review Codes Commented on in Response to the June 8, 2001 Proposed Notice)

During the comment period for our June 8, 2001 proposed notice, commenters generally supported our proposed changes. We received more than 125 comments on approximately 39 specific codes plus all the anesthesia services. The majority of these comments addressed the gastrointestinal endoscopy codes and anesthesia services.

We convened a multispecialty panel of physicians to assist us in the review of the comments. The comments we did not submit for panel review are discussed at the end of this section. The panel was moderated by our medical staff and consisted of:

- Clinicians representing the commenting specialties, based on our determination of those specialties which

are most identified with the services in question. Although commenting specialties were welcomed to observe the entire refinement process, they were only involved in the discussion of those services for which they were invited to participate.

- Primary care clinicians nominated by the American Academy of Family Physicians and the American College of Physicians and American Society of Internal Medicine.
- Four carrier medical directors.
- Four clinicians with practices in related specialties who had knowledge of the services under review.

We submitted 6 codes for evaluation by the panel. The panel discussed the work RVUs involved in each procedure under review in comparison to the work RVUs associated with other services on the fee schedule. We assembled a set of reference services and asked each panel member to compare the clinical aspects for the services they believed were incorrectly valued to one or more of the reference services. In compiling the reference set, we attempted to include—(1) services that are commonly performed whose work RVUs are not controversial; (2) services that span the entire work spectrum from the easiest to the most difficult; and (3) at least three services performed by each of the major specialties so that each specialty would be represented. The reference set listed over 300 services. Group members were encouraged to make comparisons to these reference services. The intent of the panel process was to capture each participant's independent judgement based on the discussion and his or her clinical experience. Following each discussion, each participant rated the work for the procedure. Ratings were individual and confidential; there was no attempt to achieve consensus among the panel members.

We then analyzed the ratings based on a presumption that the RVUs in the proposed notice were correct. To overcome this presumption, the inaccuracy of the proposed RVUs had to be apparent to the broad range of physicians participating in each panel.

Ratings of work were analyzed for consistency among the groups represented on each panel. We used statistical tests to determine whether there was enough agreement among the groups on the panel, and whether the agreed-upon RVUs were significantly different from the proposed RVUs published in the June 8, 2001 proposed notice. We did not modify the RVUs unless there was a clear indication for a change. If there was agreement across groups for change, but the groups did not agree on what the new RVUs should be, we eliminated the outlier group, and looked for agreement among the remaining groups as the basis for new RVUs. We used the same methodology in analyzing the ratings that we first used in the refinement process for the 1993 fee schedule. The statistical tests we used are described in detail in the November 25, 1992 final rule (57 FR 55938).

Our decision to convene a multispecialty refinement panel of physicians and to apply the statistical tests referred to above was based on our need to balance the interests of those who commented on the work RVUs against the redistributive effects that would occur in other specialties. Of the 6 codes reviewed by the multispecialty panel, all were the subject of requests for increased values.

We also received comments that we did not submit to the panels for a variety of reasons. These comments are discussed later in this section. Of the proposed codes that were reviewed, 3 increased, and 3 were not changed.

Table 4.—Work Relative Value Unit Refinements of Five-Year Review Codes Commented on in Response to the June 8, 2001 Proposed Notice

Table 4 lists the codes reviewed during the 5-year review on which we received comments. This table includes the following information:

- *CPT/HCPCS Code.* This is the CPT or alphanumeric HCPCS code for a service.
- *Modifier.* A modifier–26 is shown if the work RVUs represent the professional component of the service.
- *Description.* This is an abbreviated version of the narrative description of the code.
- *Proposed Work RVUs.* This column includes the work RVUs proposed in the June 8, 2001 proposed notice for each reviewed code.
- *Requested Work RVUs.* This column identifies the work RVUs requested by the commenters. If the commenters requested different RVUs, the table lists the highest requested RVUs. For some codes we received recommendations for an increase but no specific RVUs were recommended.
- *RUC Recommendation.* This column identifies the work RVUs recommended by the RUC if the RUC made a specific work value recommendation as part of its comments on the June 8, 2001 proposed notice.
- *2002 Work RVUs.* This column contains the 2002 work RVUs.
- *Basis for Decision.* This column indicates whether:

+ The recommendations of the multispecialty refinement panel were the basis upon which we determined that the proposed work RVUs published June 8, 2001 should be retained (indicator 1).

+ A new value emerged from our analysis of the refinement panel ratings (indicator 2).

+ A new or retained value came from review of the comment(s) received (indicator 3).

+ A new value came from the need to make a rank-order change to maintain or correct existing relationships among services (indicator 4).

+ A value is retained and the code has been referred to the RUC (indicator 5).

+ There is no change in value but we have adjusted the global period (indicator 6).

TABLE 4.—WORK RVU REFINEMENTS OF THE FIVE-YEAR REVIEW CODES COMMENTED ON IN RESPONSE TO JUNE 8, 2001 PROPOSED NOTICE

CPT/HCPCS Code [1]	Mod	Descriptor	Proposed Work RVU	Requested Work RVU	RUC REC	2002 Work RVU	Basis for decision
00100–01999		Anesthesia services	([2])	([3])		([2])	#5
11055		Trim skin lesion	0.27	0.43		0.43	#3
11056		Trim skin lesion, 2 to 4	0.39	0.61		0.61	#3
11057		Trim skin lesions, over 4.	0.50	0.79		0.79	#3
11719		Trim nail(s)	0.11	0.17		0.17	#3
27286		Fusion of hip joint	23.45			23.45	#4

TABLE 4.—WORK RVU REFINEMENTS OF THE FIVE-YEAR REVIEW CODES COMMENTED ON IN RESPONSE TO JUNE 8, 2001 PROPOSED NOTICE—Continued

CPT/HCPCS Code [1]	Mod	Descriptor	Proposed Work RVU	Requested Work RVU	RUC REC	2002 Work RVU	Basis for decision
36400		Drawing blood	0.18	0.38		0.38	#2
36405		Drawing blood	0.18	0.32		0.31	#2
38510		Biopsy/removal, lymph nodes.	6.43			6.43	#6
38571		Laparoscopy, lymphadenectomy.	12.38	19.84		14.68	#2
38740		Remove armpit lymph nodes.	10.02	10.03		10.03	#3
38745		Remove armpit lymph nodes.	13.00	13.10		13.10	#3
38760		Remove groin lymph nodes.	12.94	12.95		12.95	#3
39503		Repair of diaphragm hernia.	34.85	95.00		95.00	#3
43219		Esophagus endoscopy	2.80	3.18		2.80	#3
43239		Upper GI endoscopy, biopsy.	2.69	2.87		[1] 2.87	#3
43244		Upper GI endoscopy/ligation.	4.59	5.05		5.05	#3
43247		Operative upper GI endoscopy.	3.39	3.40		3.39	#3
43249		Esoph endoscopy, dilation.	2.90	3.25		2.90	#3
43255		Operative upper GI endoscopy.	4.40	4.82		4.82	#3
43259		Endoscopic ultrasound exam.	4.89	6.53		4.89	#3
43263		Endo cholangiopancreatograph.	6.19	7.29		7.29	#3
43265		Endo cholangiopancreatograph.	8.90	10.02		10.02	#3
43269		Endo cholangiopancreatograph.	6.04	8.21		8.21	#3
44388		Colon endoscopy	2.82	3.24		2.82	#3
44389		Colonoscopy with biopsy.	3.13	3.54		3.13	#3
44390		Colonoscopy for foreign body.	3.83	4.25		3.83	#3
44391		Colonoscopy for bleeding.	4.32	5.25		4.32	#3
44392		Colonoscopy and polypectomy.	3.82	4.23		3.82	#3
44393		Colonoscopy, lesion removal.	4.84	5.79		4.84	#3
45380		Colonoscopy and biopsy.	4.01	4.44		[1] 4.44	#3
49605		Repair umbilical lesion	22.66	76.00		76.00	#3
56515		Destruction, vulva lesion(s).	2.76	3.63		2.76	#1
56605		Biopsy of vulva/perineum.	1.10		1.10	[4] 1.10	#3
56810		Repair of perineum	4.13		4.13	[4] 4.13	#3
57500		Biopsy of cervix	0.97			0.97	#5
58100		Biopsy of uterus lining	0.71		1.53	[4] 1.53	#3
76090		Mammogram, one breast.	0.70	0.93		0.70	#1
76091		Mammogram, both breasts.	0.87	1.10		0.87	#1
G0127		Trim nail(s)	0.11			0.17	#3

[1] All CPT codes and descriptors copyright 2000 American Medical Association.

[2] No change.
[3] 26% incr.
[4] RVUS to remain interim for 2002.

C. Discussion of Comments by Clinical Area

In this section, we discuss the comments we received on the 39 codes of the more than 900 codes for which we sought public comment. For the codes for which we did not receive any comments, our proposed RVUs are being made final. We have categorized the comments into the same clinical areas we used in the June 8, 2001 notice. Within each clinical area, listed below, we discuss the comments received in CPT code order.

1. Vascular Surgery

Comment: The American Association for Vascular Surgery and the Society for Vascular Surgery expressed appreciation that we agreed with the RUC recommendations for work RVUs for the vascular surgery codes reviewed under the second 5-year review. However, it indicated that some of these services may still be undervalued. It will be reviewing these services as well as a small number of vascular surgery services that were not submitted this year and possibly submit these under the next 5-year review.

Response and final decision: We will finalize the RVUs for the vascular surgery codes as proposed.

2. General Surgery and Colon and Rectal Surgery

Family 2 Lymphadenectomy

Comment: The American College of Surgery (ACS) was supportive of the work performed by CMS medical officers to ensure that rank order anomalies were eliminated from 6 families of codes where acceptance of the RUC recommendations would create distortions in family work value relativity and the rest of the physician fee schedule.

The ACS pointed out a typographical error in the proposed notice. For Family 2 Lymphadenectomy, CMS disagreed with the RUC, and stated that the median survey result of 13 is appropriate for CPT code 38745. The ACS commented that the survey median is actually 13.10. The correction of this error would lead to increases for related family codes 38740 (from 10.02 to 10.03) and 38760 (from 12.94 to 12.95).

Response and final decision: We agree with the commenter's response and will adjust the work values for CPT code 38740 to 10.03; for CPT code 38745 to 13.10; and for CPT code 38760 to 12.95.

Family 3 Lymph Nodes and Lymphatic Channels—Incision/Excision

Comment: The American Academy of Otolaryngology recommended that CMS change the global surgical period of CPT code 38510 from 90 days to 10 days following the RUC survey data for this CPT code. It alleges that there were no postoperative visits beyond 10 days associated with this procedure for the relative work established.

Response: The RUC valued this service based on the fact that it is typically furnished to an outpatient. The value of a hospital discharge day was subtracted from the median survey value. The median survey value is based on one followup office visit. We believe there is merit to the group's point and will change the global period from 90 days to 10 days.

3. Thoracic Surgery

Comment: The Society of Thoracic Surgeons expressed appreciation that we had accepted the RUC recommendations for corrections to work values of many thoracic and cardiac procedures.

Response and final decision: We will finalize the RVUs for these codes as proposed.

4. Orthopedic Surgery

We received no comments on these codes. Therefore, we will finalize all of the proposed work RVUs for the orthopedic surgery codes. We would also note that, in the June rule, we proposed to correct a rank order anomaly by increasing values for CPT code 27286. This code, however, was inadvertently omitted from the table and addendum; it is included in Table 4 and Addendum A of this final rule.

5. Ophthalmology

We received no comments on these codes. Therefore, we will finalize all of the proposed work RVUs for the ophthalmology codes.

6. Urology

We received no comments on these codes. Therefore, we will finalize all of the proposed work RVUs for the urology codes.

7. Obstetrics/Gynecology

CPT Code 38571, Laparoscopy, Surgical; With Bilateral Total Pelvic Lympadenectomy

Comment: The Society of Gynecologic Oncologists (SGO) stated that, while we had proposed an increase for CPT code 38572, an increase was not proposed for CPT code 38571. The SGO believes that both of these codes are undervalued based on insufficient work RVUs being assigned for the laparoscopy with bilateral total pelvic lymphadenectomy procedure, which is common to both codes. It requested that a proportional increase in work RVUs be made for CPT 38571 as well.

Response: We accepted the RUC recommendation that no increase be made in the work RVU for this service based on the lack of compelling evidence to support an increase, and we had proposed retaining the current work RVU for this service. However, based on the comments received, we referred this code to a multispecialty refinement panel for review.

Final decision: As a result of our analysis of the multispecialty refinement panel ratings, we are increasing the work RVUs for CPT code 38571 to 14.68 work RVUs.

CPT Code 56515, Destruction of Lesion(s), Vulva; Extensive, Any Method

Comment: For CPT code 56515, SGO disagreed with the rationale that CPT codes 56515 and 46924 have comparable physician and intraservice work time. It indicated that CPT code 56515 involves lasering a much larger area; therefore, the amount of intraservice time and the number of postoperative visits can be significantly higher.

Response: We had accepted the RUC recommendation of 2.76 work RVUs for this code which was lower than the 3.625 which had been requested by the specialty. Based on the comments received, we referred this code to a multispecialty refinement panel for review.

Final decision: As a result of our analysis of the refinement panel ratings, we are retaining the work RVU of 2.76.

CPT Code 57500, Biopsy, Single or Multiple, or Excision of Lesion, With or Without Fulguration (Separate Procedure)

Comment: In addition to comments on the 2 codes referenced above, SGO also recommended that, while CPT code 57500 was not considered part of the 5-year review, this gender-specific code be forwarded to the RUC for evaluation. It believes the amount of physician time and level of pre- and postoperative work for this procedure is similar to that for the male-specific procedures of CPT

code 54100 (Biopsy of penis (separate procedure)), and CPT code 54505 (Biopsy of testis, incisional (separate procedure)), and thus the physician work for CPT code 57500 should be increased.

Response and final decision: We will refer this code to the RUC for review.

Comment: In our June 8, 2001 proposed notice, we also stated that we referred three female-specific procedure codes that appeared to be misvalued to the RUC for review. As part of its comments on the proposed notice, and in response to our request to review these services, the RUC has provided recommendations on work RVUs for the three codes as follows:

• *CPT code 56605, Biopsy of vulva or perineum (separate procedure); one lesion.*

The RUC stated that this code was reviewed during the first 5-year review and was increased at that time to double the original work RVU for CPT code 56605. While the current work RVU for this code is less than CPT code 54100, Biopsy of penis (WRVU 1.90), the structure of CPT code 56605 allows additional reporting when more than one lesion is biopsied, while the penile code (54100) may be only reported once, regardless of the number of biopsies. The RUC recommended that the current work RVU of 1.10 be maintained for CPT code 56605.

• *CPT code 56810, Perineoplasty, repair of perineum, nonobsterical (separate procedure).*

The RUC indicated that the specialty stated that this service may be undervalued; however, perineoplasty is performed so rarely as a separate procedure that it would be difficult to obtain valid survey data to appropriately value this service. In addition, the specialty is currently considering CPT revisions to this family of codes and will review this issue at that time. The RUC recommended that the current work RVU of 4.13 be maintained for the service.

• *CPT code 58100, Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure).*

The RUC indicated that, based on a review of survey data, CPT code 58100 is undervalued. The RUC compared this code to CPT code 55700 and determined that these 2 services are similar in time and intensity. The RUC also agreed that 58100 is more work than the reference procedure, CPT code 57505, and recommended an increase in the work RVU for CPT code 58100 to 1.53. The RUC also provided refinements to the practice expense inputs for this code.

Response and final decision: We agree with the RUC recommendations for these three codes and will maintain the current work RVUs of 1.10 for CPT code 56605 and 4.13 for CPT code 56810 and increase the work RVUs for CPT code 58100 to 1.53. Because the public has not had a chance to comment on these work RVUs, we will consider them to be interim and will accept comments on values for these 3 codes.

8. Gastroenterology

In the June 8, 2001 proposed notice, we explained that, for the selected series of gastrointestinal endoscopy codes for the 5-year review, the RUC recommended increases in work RVUs for some of the codes and no change in work for other codes. While some of these endoscopy codes may be misvalued, we proposed to keep all work RVUs for gastrointestinal endoscopy codes unchanged. We also requested that the RUC perform a comprehensive review of all gastrointestinal endoscopy codes to ensure that all codes are properly valued and that no rank-order anomalies within and across specialties are created or exacerbated.

With respect to the RUC recommendation concerning permitting separate reporting and payment of conscious sedation codes 90141 and 90142, we stated we would be reviewing data concerning this issue. Any proposal we would have concerning payment and reporting of conscious sedation codes would be the subject of future rulemaking.

Comment: Many physicians and several medical organizations expressed concern about our decision to propose no changes for the 17 endoscopy codes for which the RUC had recommended increases. The American Society for Gastrointestinal Endoscopy, the American College of Gastroenterology, and the American Gastroenterological Association provided an extensive discussion on each of the codes which we will summarize and respond to below.

CPT Code 43219, Esophagoscopy, Rigid or Flexible; With Insertion of Plastic Tube or Stent

The RUC recommended an increase in work RVUs from 2.8 to 3.18 for CPT code 43219 based upon the increased complexity of the condition of the patients receiving these stents. We proposed to maintain the current work RVUs due to our concerns about creating rank order anomalies in the fee schedule.

Comment: We received comments regarding this code from several societies representing gastroenterologists who said that the incremental work involved with esophageal stent placement, presently valued at 1.21 RVUs, should be increased to 1.59 RVUs. The commenters agreed with CMS that several other stent codes were recently reviewed by the RUC and valued using the incremental work value of 1.21 RVUs. Increasing the incremental work value for CPT code 43219 to 1.59 RVUs would result in rank order anomalies for several codes. The commenters acknowledged that these anomalies resulted from the timing of the 5-year review and the valuation of new stent placement codes. In spite of this, the commenters felt the RUC-recommended value was appropriate.

Response: We feel the current work increment of 1.21 RVUs for placement of a stent over the base code 43200 is the appropriate value when assessing incremental work. We do not agree that the incremental work for stent placement should be increased to 1.59 RVUs. The upper GI endoscopy base CPT code 43235 has RVUs of 2.39 and CPT code 43256, upper GI endoscopy with stent placement (including predilation) has work RVUs of 4.35. This results in an incremental value of 1.96 RVUs which includes placement of the stent (1.21 RVUs) and predilation (0.75 RVUs).

Furthermore, diagnostic bronchoscopy, CPT code 31622, has work RVUs of 2.78, and bronchoscopy with tracheal dilation and placement of a tracheal stent (CPT code 31631) has an RVU of 4.37. This means that the incremental work value for tracheal dilation and stent placement is 1.59 RVUs which is significantly less than the work increment of 1.96 listed for CPT code 43256. We also note that CPT code 43219 will be billed with CPT code 43226 (dilation of the esophagus over a guidewire) which has an incremental value of 0.75 work RVUs. This means that when an esophageal stent is placed, the total work value is 1.59 (base code) plus 1.21 (stent placement) plus 0.75 (dilation) for a total of 3.55 RVUs.

More important, the incremental work of placing the stent is 1.96 RVUs which is similar to the incremental work of placing a stent elsewhere in the GI tract and more than the incremental work of placing a stent in the trachea. Increasing the incremental work of placing an esophageal stent to 1.59 RVUs from 1.21 would create a significant rank order anomaly in the physician fee schedule because esophageal stent placement would be valued more than stent placement elsewhere.

Lastly, we note that less work is required to place a plastic stent than to place a wire stent. Both, however, are coded using CPT code 43219 and are valued similarly. For these reasons, we have decided to maintain the current RVUs of 2.80 for this code, and we would like the RUC to review all of the GI endoscopic stent placement codes and all of the GI endoscopic dilation codes simultaneously. Because these services are performed by gastroenterologists and various surgical specialties (general surgery, thoracic surgery, otolaryngology, and colorectal surgery), the RUC should obtain input from all specialties performing these services.

CPT Code 43239, Upper Gastrointestinal Endoscopy Including Esophagus, Stomach, and Either the Duodenum and/or Jejunum as Appropriate, With Biopsy, Single or Multiple

The RUC recommended an increase in work RVUs from 2.69 to 2.87 based on an increase in the number of biopsies obtained during each procedure. The RUC also stated that technological advances allowing for greater precision and detail in finding abnormalities have increased the complexity of this service. The RUC also stated that technological advances have allowed results to be reported more quickly which increases the postservice work because biopsy information and treatment guidance are conveyed to the patient the same day as the procedure. We disagreed, and in the June rule we proposed to maintain the current work RVUs.

Comment: We received comments from several societies representing gastroenterologists and the following concerns were expressed: First, they did not feel that the work of performing biopsy procedures at different sites in the GI tract was the same. They commented that biopsy of lesions in different anatomic sites required different amounts of work. Second, they felt that even though CPT code 43239 was used to report both single and multiple biopsies, the typical patient requires multiple biopsies.

Response: We reviewed these comments and compared the intraservice time for this procedure to other endoscopic biopsy procedures and we have decided to accept the RUC recommendations for this code. However, we are making this value interim. Please see the discussion under CPT code 45380 regarding this issue.

CPT Code 43244, Upper Gastrointestinal Endoscopy Including Esophagus, Stomach, and Either the Duodenum and/or Jejunum as Appropriate; With Band Ligation of Esophageal and or Gastric Varices; CPT Code 43255, Upper Gastrointestinal Endoscopy Including Esophagus, Stomach, and Either the Duodenum and/or Jejunum as Appropriate; With Control of Bleeding, Any Method

The RUC recommended an increase in work RVUs for CPT code 43255 from 4.4 to 4.82 work RVUs, based on the use of new technology, such as lasers, to control bleeding. The RUC also recommended an increase in work RVUs for CPT code 43244 from 4.59 to 5.05 RVUs, based on the increased number of bands typically used to treat esophageal varices. We disagreed and proposed to maintain the current work RVUs.

Comment: We received comments from several societies representing gastroenterologists and the following concerns were expressed: First, they felt that we had incorrectly determined that these two services should be valued identically because the RUC stated that they were ''similar'' in terms of work. Second, although they acknowledged that the use of cautery to control bleeding is not new, they said that the service is undervalued irrespective of which method is used to control bleeding.

Response: We reviewed these comments and compared the intraservice time to other similar procedures and have decided to accept the RUC recommendations for the above CPT codes.

CPT Code 43247, Upper Gastrointestinal Endoscopy Including Esophagus, Stomach, and Either the Duodenum and/or Jejunum as Appropriate; With Removal of Foreign Body

The RUC recommended an increase in work RVUs for this CPT code from 3.39 to 3.59 work RVUs, based on increased complexity of patients undergoing this procedure with a concomitant increase in risk of morbidity. We disagreed and proposed to maintain the current work RVUs.

Comment: We received comments from several societies representing gastroenterologists with the following concerns: First, they felt the increase in the work RVU for this procedure was justified because the procedure is usually performed under emergent conditions. Second, they did not favor uniform incremental work values for removal of foreign bodies from different sites in the gastrointestinal tract.

Response: The RUC used a building-block approach to validate its acceptance of the median work RVUs from the survey. We do not believe the approach used by the RUC is valid for this CPT code. We compared this service to other similar services and continue to believe that the RUC recommendation does not represent the appropriate work increments for foreign body removal from various gastrointestinal sites. Furthermore, it would create a clear rank-order anomaly with CPT code 43215 that should have an identical work increment. Therefore, we will maintain the current work RVUs for this procedure. If the RUC reviews this service again, we ask that all GI endoscopic services for removal of foreign bodies be included in the review.

CPT Code 43249, Upper Gastrointestinal Endoscopy Including Esophagus, Stomach, and Either the Duodenum and/or Jejunum as Appropriate; With Balloon Dilation

The RUC recommended an increase from 2.9 to 3.35 work RVUs for this CPT code based on increased complexity of the condition of patients undergoing this procedure. We disagreed and proposed to maintain the current work RVUs.

Comment: We received comments from several organizations representing gastroenterologists who felt the increase in incremental work value was justified based on their survey. However, they admitted that revaluing CPT code 43249 would create a rank order anomaly with CPT code 43220, an identical procedure. They stated that CPT code 43220 is also undervalued.

Response: The current work increment for ''balloon dilation of esophagus (less than 30mm diameter)'' is 0.51 RVUs for both the esophagus and upper gastrointestinal endoscopy families. Since this is the same procedure in both families, it is unclear why the work should be increased for the upper gastrointestinal family only. This would create a rank-order anomaly. We have decided to maintain the current work RVUs for CPT code 43249. We plan to ask the RUC to review the incremental work RVUs for both CPT code 43249 and CPT code 43220.

CPT Code 43259, Upper Gastrointestinal Endoscopy Including Esophagus, Stomach, and Either the Duodenum and/or Jejunum as Appropriate; With Endoscopic Ultrasound Examination

The RUC recommended an increase in work RVUs from 4.59 to 8.59 based on the complexity of the equipment and the skill and judgement required. The

RUC also noted that the survey results supported this procedure as requiring more work than CPT code 43260—diagnostic endoscopic retrograde cholangio-pancreatography (ERCP)—which has 5.96 work RVUs.

Comment: We received comments from several societies representing gastroenterologists who agreed with us that the RUC values for the new endoscopic ultrasound codes (EUS) were inconsistent with the value recommended by the RUC for CPT code 43259. They felt that new survey data should have been used by the RUC when valuing CPT code 43259 instead of the current incremental work values used by the RUC for the 5-year review.

Response: The RUC used the following building-block methodology to arrive at its recommendation for 43259—1) The RUC added 1.5 work RVUs, which is approximately 75 percent of the difference between the RUC recommendation from the last 5-year review (6.11 work RVUs) and the work RVUs that we assigned (4.0 work RVUs); (2) the RUC then added 2.2 work RVUs, which are the work RVUs of CPT code

93312 (Echocardiography, Transesophageal, Real Time With Image Documentation (2D) (With or Without M-Mode Recording); Including Probe Placement, Image Acquisition, Interpretation and report)

Not only do we disagree with the RUC methodology for this recommendation, but we also note that the RUC has used the current work RVUs for CPT code 43259 to value not only other gastrointestinal transendoscopic ultrasound procedures but also many transendoscopic ultrasound guided biopsy codes. We also note that the RUC has recently re-evaluated CPT code 43231, Esophagoscopy, rigid or flexible; with endoscopic ultrasound examination, and recommended much lower RVUs for the incremental work of the ultrasound examination. Therefore, accepting the RUC recommendation for this code would be inconsistent with the RUC's reevaluation of CPT code 43231, would invalidate the work valuation of many other gastrointestinal endoscopy codes, and would create numerous rank-order anomalies. Therefore, we recommend that the RUC review CPT code 43259 along with all the other endoscopic ultrasound examination codes and all the transendoscopic ultrasound guided biopsy codes.

CPT Code 43263, Endoscopic Retrograde Cholangio-pancreatography (ERCP); With Pressure Measurement of Sphincter of Oddi (Pancreatic Duct or Common Bile Duct)

CPT Code 43265, Endoscopic Retrograde Cholangio-pancreatography (ERCP) With Endoscopic Retrograde Destruction, Lithotripsy of Stone(s), Any Method

CPT Code 43269, Endoscopic Retrograde Cholangio-pancreatography (ERCP); With Endoscopic Retrograde Removal of Foreign Body and/or Change of Tube or Stent

The RUC recommended an increase in work RVUs from 6.19 to 7.29 for CPT code 43263 based on the need to measure pressures in both the biliary and pancreatic sphincters, as well as the need for prolonged postoperative monitoring.

The RUC recommended an increase in work RVUs from 8.9 to 10.02 for CPT code 43265 based on a rank-order anomaly with code 43264 because this procedure is considered to be more time-consuming and complex than CPT code 43264.

The RUC recommended an increase in work RVUs from 6.04 to 8.21 for CPT code 43269 based on a rank-order anomaly between this code and CPT code 43268.

Comment: We received comments on these three codes from several organizations representing gastroenterologists. It was their position that these codes were commonly performed, undervalued procedures and that the survey data the organizations provided justify the increase in RVUs. We disagreed and proposed to maintain the current work RVUs for these three codes.

Response: We have reviewed the codes and compared their intraservice times to other similar procedures and have decided to accept the RUC recommendations.

CPT Code 44388, Colonoscopy Through Stoma; Diagnostic With or Without Collection of Specimen(s) by Brushing or Washing (Separate Procedure)

CPT Code 44389, Colonoscopy Through Stoma; With Biopsy, Single or Multiple

CPT Code 44390, Colonoscopy Through Stoma; With Removal of Foreign Body

CPT Code 44391, Colonoscopy Through Stoma; With Control of Bleeding, any Method

CPT Code 44392, Colonoscopy Through Stoma; With Removal of Tumor(s), Polyp(s), or Other Lesion(s) by Hot Biopsy Forceps or Bipolar Cautery

CPT Code 44393, Colonoscopy Through Stoma: With Ablation of Tumor(s), Polyp(s), or Other Lesion(s) Not Amenable to Removal by Hot Biopsy Forceps, Bipolar Cautery or Snare Technique

These 6 codes are in the same family, and the RUC recommended an increase for each code in this family primarily because it felt that the base CPT code, 44388, should be valued the same as CPT code 45378, diagnostic colonoscopy, at 3.7 work RVUs. The RUC also recommended that the values for the other codes in this family be increased to maintain their relativity to CPT code 44388. We disagreed and proposed to maintain the current work RVUs for all codes in this family.

Comment: We received comments from several societies representing gastroenterologists who commented that, although performing a colonoscopy through a stoma involves less physician work than performing a standard colonoscopy, they believed that performing a colonoscopy through a stoma is more technically challenging than performing a standard colonoscopy.

Response: We disagree with valuing the performance of a colonoscopy through a stoma identically to performing a standard colonoscopy. We feel the proposed valuation creates a series of rank-order anomalies. Consequently, we will finalize our proposal to maintain the current RVUs for this family of codes. In addition to determining that the RUC recommendation for the base code 44388 was incorrect, we note that the RUC recommendations create increments of work for performance of ''biopsy, single or multiple,'' ''control of bleeding, any method,'' ''removal of tumors,'' and ''ablation of tumors'' during a colonoscopy through a stoma, which are inconsistent with the same increments for the complete colonoscopy family of codes that begins

with code 45378. We note that, in addition to gastroenterologists, general surgeons and colorectal surgeons perform these procedures. Therefore, if the RUC reconsiders the work values of these codes, we believe that information should be obtained from all physicians who perform these services.

CPT Code 45380, Colonoscopy, Flexible Proximal to Splenic Flexure; With Biopsy, Single or Multiple

The RUC recommended an increase in work RVUs from 3.98 to 4.44 for this CPT code, based on the increased number of biopsies generally taken during this procedure and the increased difficulty in removing these polyps. We disagreed and proposed to maintain the current work RVUs for this service.

Comment: We received comments from several societies representing gastroenterologists who commented that work increments for performing biopsies at different sites within the gastrointestinal tract are different. Furthermore, the societies believe that the incremental work of biopsy procedures performed by different specialties (for example, gastrointestinal endoscopic biopsies and tracheobronchial endoscopic biopsies) need not be valued identically. They also note that even though this code is reported for both single and multiple biopsies, the ''typical'' patient usually has multiple biopsies performed.

Response: We have reviewed these comments and compared the intraservice time of this code to the intraservice time of other similar procedures. We have decided to accept the RUC recommendation. However, CMS believes the best approach to accurately value gastrointestinal endoscopy biopsy procedures is to evaluate all the biopsy procedures in the gastrointestinal tract. This would provide the opportunity to establish the correct incremental work RVUs and avoid creating rank-order anomalies. Therefore, we will make the work values for CPT code 43239 (as indicated earlier) and 45380, interim until we receive further recommendations from the RUC regarding the entire spectrum of gastrointestinal biopsy procedures.

9. Conscious Sedation

Comment: The American Academy of Family Physicians indicated that the RUC has appointed an ad hoc workgroup to review the issue of conscious sedation, including identifying codes where conscious sedation is not inherently included as a component of the physician work. It recommended that, when the workgroup and RUC complete this review, we allow separate reporting and payment for CPT codes 90141 and 90142 in conjunction with the identified codes. The AMA and the RUC also referred to the newly formed workgroup in their comments, and the AMA urged us to work with the RUC and the CPT to reach a solution on the coding and payment issues surrounding conscious sedation.

Response and Final Decision: We welcome suggestions on this issue from both the coding and payment perspective. When the workgroup review of these issues is complete, we will evaluate any recommendations we receive for the development of any future proposals.

10. Pulmonary Medicine/Critical Care

We received no comments on these codes. Therefore, we will finalize the proposed work RVUs for the pulmonary medicine and critical care codes.

11. Cardiology

CPT Code 93350, Transthoracic Echocardiography

Comment: The American College of Cardiology expressed appreciation of our acceptance of the RUC recommendation to increase the work RVUs for this code.

Response and Final Decision: We are finalizing the proposed RVUs for CPT code 93350 and maintaining the work values for the other 2 CPT codes, 32234 and 32235, as discussed in the proposed notice.

12. Pediatrics

CPT Code 36400 (Venipuncture Under Age 3 Years; Femoral, Jugular or Sagittal Sinus) and CPT Code 36405 (Venipuncture, Under Age 3 Years, Scalp Vein)

Comment: The American Academy of Pediatrics (AAP) disagreed with our recommendations for CPT codes 36400 and 36405. The RUC recommended work RVUs of .38 and .32, respectively. We proposed that the work RVUs remain unchanged at .18 for each code. We do not believe it is appropriate to compare the work RVUs of a venipuncture to the work of an evaluation and management service. The AAP pointed out that the work involved in providing a venipuncture to a patient under age 3 is more intense than it has been in the past.

Response: Based on the comments received, we referred this code to a multispecialty refinement panel for review.

Final decision: As a result of our analysis of the multispecialty refinement panel ratings, we are increasing the work RVUs for CPT code 36400 to 0.38 and also increasing the work RVUs for CPT code 36405 to 0.31.

13. Pediatric Surgery

CPT Code 39503 (Repair, Neonatal Diaphragmatic Hernia, With or Without Chest Tube Insertion and With or Without Creation of Ventral Hernia) and CPT Code 49605 (Repair of Large Omphalacele or Gastroschisis; With or Without Prosthesis)

Comment: The AAP and the American Pediatric Surgical Association (ASPA) recommend that codes 39503 (Repair, neonatal diaphragmatic hernia, with or without chest tube insertion and with or without creation of ventral hernia), and 49605 (Repair of large omphalacele or gastroschisis; with or without prosthesis) receive interim values of 95 and 76, respectively, until the issue of critical care in the postoperative period is resolved. We had proposed to maintain the current work RVUs of 37.54 and 24.94, respectively, as interim 2002 work values and asked the RUC to resubmit recommendations for work RVUs for CPT codes 39503 and 49605 with either a 000 or 010 global period. As an option, pending resolution of the critical care issue, the APSA recommended that the interim work values for CPT codes 39503 and 49605 be 46.35 and 30.14, respectively.

The RUC agreed that the physician work in the postoperative period caring for these seriously ill neonates was significant and required the services of both surgeon and the neonatologist. The RUC requests that CMS treat these codes in the same manner as the other 90-day global codes that include extensive postoperative care.

Response: Upon further review, we agree with the RUC's recommendation and will establish the work values for CPT codes 39503 and 49605 at 95 and 76 units, respectively.

14. Radiology

CPT Code 76090, Mammography; Unilateral and CPT Code 76091 Mammography; Bilateral

Comment: The American College of Radiology (ACR) requested that CMS increase the work RVUs for unilateral mammography, that is, CPT code 76090, from the proposed .70, to .93 and for bilateral mammography, that is, code 76091, from the proposed .87, to 1.10. The ACR believes these values, which are the median survey values, more accurately reflect the work involved with these two procedures. The ACR points out that there is a significant amount of physician time associated

with reviewing the results with these anxious patients and complying with the mandatory Mammography Quality Standards Act requirements.

The ACR commented that the chart at 66 FR 31045 of the June 8, 2001 proposed rule indicates that CPT code 76005 had a RUC recommendation of 10.60. However, that column should read .60.

The ACR also took exception to the requested work RVUs reported in the chart at 66 FR 31045 for codes 76065, 76090 and 76091. The chart displayed requested work RVUs of .60 for 76065, .64 for 76090, and .76 for code 76091. The ACR asked that the chart be corrected to reflect the actual requested work RVUs for each code. These corrected values, based on the median survey values, are .70 for CPT code 76065, .93 for 76090, and 1.10 for CPT code 76091.

Response: Based on the comments received, we referred these codes to a refinement panel for review. We regret the error in the chart concerning the requested work RVUs.

Final decision: As a result of our analysis of the multispecialty panel ratings, we are retaining the work RVU of 0.70 for CPT code 76090 and 0.87 for CPT code 76091, the work RVUs we proposed in the June 8 proposed rule.

CPT Code 76092, Screening Mammography, Bilateral Two View Film Study of Each Breast

In addition, we had requested the RUC to review the work RVUs for code 76092 (Screening mammography, bilateral two view film study of each breast). In its comments on the June 8, 2001 proposed rule, the RUC indicated it had placed this issue on the September 2001 meeting agenda and would provide recommendations to us following that meeting. The September meeting had to be cancelled and the issues to be addressed at that meeting will be discussed at the first meeting early next year. Therefore, we are finalizing the current RVUs for this code.

15. Plastic Surgery

We received no comments on these codes. Therefore, we will finalize the proposed work RVUs for the plastic surgery codes.

B. Other Comments

1. Anesthesia Services

In our June 8, 2001 proposed rule (66 FR 31065), we stated that the American Society of Anesthesiologists (ASA) contended that the work of anesthesia services is undervalued and, based on discussions with the RUC, the ASA requested a 24 percent increase in anesthesia work. However, the RUC furnished no recommendation on anesthesia services; instead, it assigned to a newly created workgroup the responsibility for reviewing anesthesia services in the context of the physician fee schedule. We indicated that the ASA will be working with this workgroup on clinical issues, such as induction and postinduction intensity, and did not propose any changes to the anesthesia CF at this time to reflect the 5-year review of physician work for anesthesia services. However, we did indicate that we might make changes in response to recommendations the RUC may provide.

Comment: Many individual anesthesiologists commented that their services are undervalued. The American Society of Anesthesiologists also commented that its services are undervalued and asked that we accept the results of the first RUC workgroup (weighted average increase of 26 percent on representative codes) and extrapolate this to all anesthesia codes. We also received letters from individuals indicating that anesthesia services are undervalued.

In its comments, the RUC stated that it had not come to an agreement on extrapolating the results of the work of the 19 studied anesthesia codes to all anesthesia codes. The RUC agreed that the five quintiles for postinduction anesthesia and the examples associated with each quintile were appropriate. The RUC also examined the intensity values assigned to each quintile and made adjustments to the intensity values based on comparisons to evaluation and management codes and critical care services. It agreed to the following values—.224 for Level 1; .031 for Level 2; .051 for Level 3; .070 for Level 4; and .085 for Level 5.

The RUC approved the following intensity factors for the induction period—.067 for induction of general anesthesia; .067 for induction of spinal and epidural anesthesia; and .051 for induction of regional anesthesia.

Although the RUC recommended acceptance of the building block work values for the 19 codes studied, it did not resolve issues related to how often anesthesiologists provide the retrobulbar bloc for code 00142 and agreed that the distribution of postinduction time among the quintiles should be reviewed in more detail after it receives more input from surgical specialties.

Response and final decision: The RUC has informed us that it will continue to look at anesthesia work beginning at its first meeting in CY 2002. We will review the RUC recommendation and address anesthesia work in next year's proposed physician fee schedule rule.

2. Spine Injection Procedures

We received no comments on these codes. Therefore we will finalize the proposed work RVUs for the spine injection procedure codes.

3. Biofeedback

We received no comments on these codes. Therefore, we will finalize the proposed work RVUs for the biofeedback codes.

4. Surgical Management of Burn Wounds

We received no comments on these codes. Therefore, we will finalize the proposed work RVUs for the codes involving surgical management of burn wounds.

5. Transplantation

We received no comments on these codes. Therefore, we will finalize the proposed work RVUs for the transplantation codes.

6. Arthroscopy Services

We received no comments on these codes. Therefore, we will finalize the proposed work RVUs for the arthroscopy service codes.

7. Wheelchair Management

We received no comments on these codes. Therefore, we will finalize the proposed work RVUs for the wheelchair management codes.

8. Psychological Testing

We received no comments on these codes. Therefore, we will finalize the proposed work RVUs for the psychological testing codes.

9. Podiatric Services

In our June 8, 2001 proposed notice (66 FR 31067), we stated the American Podiatric Medical Association (APMA) submitted 5 codes (trim skin lesions/trim nails) for review (11719, 11055, 11056, 11057, and G0127) and that the HCPAC requested we review our current utilization data to ensure that the original utilization assumptions were correct. The HCPAC recommended that the current review of data should be based on actual 1999 utilization data since these codes were not fully implemented until April 1, 1998. We stated that we would review the utilization data associated with the aforementioned codes to ensure the original assumptions are still correct and that we would publish our decision in the final rule.

Comment: The APMA was pleased that we would review the utilization data; however, it indicated that the work RVUs should not be revised based on current utilization. It recommended that we accept the original RUC recommendations since these values were based on the results of surveys of practicing podiatrists that were considered and approved by the RUC.

Response and final decision: Based on our review of the data and the APMA recommendation that we accept the original RUC recommended values, we are increasing the work values for these services as follows:

- *CPT code 11719, Trimming of nondystrophic nails, any number*, a work RVU of 0.17.
- *CPT code 11055, Paring or cutting of benign hyperkeratotic lesion (for example, corn or callus) single lesion*, a work RVU of 0.43.
- *CPT code 11056, two to four lesions*, a work RVU of 0.61.

CPT code 11057, more than four lesions, a work RVU of 0.79 .

For *HCPCS code G0127, Trim nails*, while we did not receive a RUC recommendation on this code (since we created the code), we are increasing the work RVU to 0.17 to be consistent with the increase made to CPT code 11719.

D. Other Issues

1. Critical Care Services in a Global Period

The June 8, 2001 proposed rule included a discussion on critical care services (66 FR 31067–68). We stated that current Medicare policy allows separate payment to the surgeon for postoperative critical care services during the surgical global period only when the patient has suffered trauma or burns. If the surgeon provides critical care services during the global period, for reasons unrelated to the surgery, that is separately payable as well. However, the approach the RUC used for the 5-year review had previously been used to validate postoperative work. That approach compared the work of a postoperative intensive care unit visit by the surgeon to code 99291, *Critical care, evaluation and management of the critically ill or critically injured patient, first 30–74 minutes*, which is valued at 4.00 work RVUs, rather than comparing a level three subsequent hospital visit (code 99233), which is valued at 1.51 work RVUs).

We indicated that valuing the surgeon's postoperative intensive care unit visits as critical care services had raised a number of issues that could require a change in payment policy to ensure that postoperative critical care is appropriately paid. In order to ensure that we make appropriate payments to physicians furnishing postoperative critical care services to Medicare beneficiaries, we specifically solicited information and comments on several questions and issues. We also proposed that the work RVUs for those surgical codes where any postoperative intensive care unit visits were valued as critical care remain interim, until we address the issues discussed above.

Many individual physicians, specialty societies, and health benefit programs provided comments and addressed the points we had outlined in the proposed notice. We appreciate their responses and will carefully review this information as we determine whether to make a future proposal.

2. Budget Neutrality

As explained in the proposed rule published June 8, 2001 (66 FR 31068–69), section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make across-the-board adjustments to preserve budget neutrality. Based on the proposed changes in work RVUs, we indicated that budget-neutrality adjustments would be required. We proposed to reduce the conversion factor to meet the budget neutrality requirement, rather than applying a reduction to all work RVUs. We also indicated that revisions in payment policies, including the establishment of interim and final RVUs for coding changes contained in a separate proposed rule, might result in additional budget-neutrality adjustments.

Comment: The American Academy of Family Physicians, American College of Radiology, American College of Physicians, American Society for Internal Medicine, and the American Medical Association Specialty Society RVUs Update Committee indicated that they supported our proposal to maintain budget neutrality by adjusting the conversion factor.

Response and final decision: We will proceed with our proposal to maintain budget neutrality by adjusting the conversion factor.

V. Refinement of Relative Value Units for Calendar Year 2002 and Responses to Public Comments on Interim Relative Value Units for 2001

A. Summary of Issues Discussed Related to the Adjustment of Relative Value Units

Section V.B of this final rule describes the methodology used to review the comments received on the RVUs for physician work and the process used to establish RVUs for new and revised CPT codes. Changes to codes on the physician fee schedule (Addendum B) are effective for services furnished beginning January 1, 2002.

B. Process for Establishing Work Relative Value Units for the 2002 Fee Schedule and Clarification of CPT Definitions

Our November 1, 2000 final rule on the 2001 physician fee schedule (65 FR 65376) announced the final work RVUs for Medicare payment for existing procedure codes under the physician fee schedule and interim RVUs for new and revised codes. The RVUs contained in the rule applied to physician services furnished beginning January 1, 2001. We announced that we considered the RVUs for the interim codes to be subject to public comment under the annual refinement process. In this section, we summarize the refinements to the interim work RVUs that have occurred since publication of the November 2000 final rule and our establishment of the interim work RVUs for new and revised codes for the 2002 fee schedule.

1. Work Relative Value Unit Refinements of Interim and Related Relative Value Units

a. Methodology (Includes Table 5, Refinements of the 2001 Interim Work Relative Value Units)

Although the RVUs in the November 2000 final rule were used to calculate 2001 payment amounts, we considered the RVUs for the new or revised codes to be interim. We accepted comments for a period of 60 days. We received substantive comments from many individual physicians and several specialty societies on 52 CPT codes with interim work RVUs. Only comments on codes listed in Addendum C of the November 2000 final rule were considered.

We used a process similar to the process used in 1997 to address substantive comments. (See the October 31, 1997 final rule on the physician fee schedule (62 FR 59084) for the discussion of refinement of CPT codes with interim work RVUs.) We convened